NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
LITTERA SCRIPTA MANET
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Pages 45387–45962

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 81 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**
Single copies/back copies:	
Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**
FEDERAL AGENCIES	
Subscriptions:	
Assistance with Federal agency subscriptions:	
Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Printed on recycled paper.

Contents

Federal Register
Vol. 81, No. 135
Thursday, July 14, 2016

Agency for Healthcare Research and Quality

NOTICES
Supplemental Evidence and Data for Systematic Reviews Request on Osteoarthritis of the Knee: An Update, 45502–45504

Agricultural Marketing Service

NOTICES
U.S. Standards for Grades of Catfish and Catfish Products, 45449–45450

Agriculture Department

See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Food Safety and Inspection Service

Alcohol, Tobacco, Firearms, and Explosives Bureau

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Application for an Amended Federal Firearms License, 45534–45535

Animal and Plant Health Inspection Service

RULES
Importation of Mangoes from India; Technical Amendment, 45387
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  National Animal Health Monitoring System; Antimicrobial Use Studies, 45450–45451
Environmental Assessments; Availability, etc.:
  Biological Control of Cape-Ivy, 45451

Centers for Disease Control and Prevention

NOTICES
Charter Renewals:
  National Institute for Occupational Safety and Health, Safety and Occupational Health Study Section, 45504
Meetings:
  Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), 45504–45505
  Disease, Disability, and Injury Prevention and Control Special Emphasis Panel, 45506–45507
Requests for Nominations:
  Candidates and Suggested Meeting Topics for the Clinical Laboratory Improvement Advisory Committee, 45506

Centers for Medicare & Medicaid Services

PROPOSED RULES
Medicare Program:
  Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; etc., 45604–45788

Coast Guard

RULES
Safety Zones:
  Tall Ships Challenge Great Lakes 2016, Fairport Harbor, OH, Bay City, MI, Chicago, IL Green Bay, WI, Duluth, MN, Erie, PA, 45414–45416
PROPOSED RULES
Anchorage Regulations:
  Special Anchorage Areas, Marina del Rey Harbor, CA, 45428

Commerce Department

See International Trade Administration
See National Oceanic and Atmospheric Administration

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 45455

Defense Department

RULES
Federal Acquisition Regulations:
  Federal Acquisition Circular 2005–89; Small Entity Compliance Guide, 45868–45869
  Federal Acquisition Circular 2005–89; Introduction, 45832–45833
  FPI Blanket Waiver Threshold, 45854–45855
  OMB Circular Citation Update, 45852–45854
  Revision to Standard Forms for Bonds, 45855–45866
  Small Business Subcontracting Improvements, 45833–45851
  Technical Amendments, 45866–45868
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Right of First Refusal of Employment, 45502

Education Department

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Student Aid Internet Gateway (SAIG) Enrollment Document, 45461

Energy Department

See Federal Energy Regulatory Commission

RULES
Energy Conservation Program: Enforcement of Regional Standards for Central Air Conditioners, 45387–45405

Environmental Protection Agency

RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
  North Carolina; Fine Particulate Matter National Ambient Air Quality Standards Revision, 45421–45423
  Washington: Spokane Second 10-Year Carbon Monoxide Limited Maintenance Plan, 45417–45419
Determinations of Attainment:
  Atlanta, Georgia; 2008 Ozone National Ambient Air Quality Standards, 45419–45421
Significant New Use Rules on Certain Chemical Substances; Withdrawal, 45416–45417

PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
  Alabama; Infrastructure Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standard, 45428–45438
  North Carolina; Fine Particulate Matter National Ambient Air Quality Standards Revision, 45447
  Tennessee Infrastructure Requirements for the 2010 Nitrogen Dioxide National Ambient Air Quality Standard, 45438–45447
NOTICES
Meetings:
  Science Advisory Board Environmental Economics Advisory Committee; Public Teleconferences, 45475–45476
Registration Reviews:
  Alpha-chlorohydrin and Hydrogen Cyanamide; Interim Decisions, 45476–45477
  Sulfonylureas and Certain Other Pesticides; Proposed Decisions, 45477–45479

Equal Employment Opportunity Commission

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Revision of the Employer Information Report, 45479–45497

Federal Aviation Administration

RULES
Amendment of Class E Airspace and Revocation of Class E Airspace:
  De Quincy, Minden, Slidell, and Homer, LA, 45407–45409
Special Conditions:
  American Airlines, Boeing 777–200 Series Airplanes; Dynamic Test Requirements for Single-Occupant Oblique (Side-Facing) Seats Equipped with Inflatable Lapbelts, 45405–45407
PROPOSED RULES
Safety Management System for Certificated Airports, 45872–45909

Federal Bureau of Investigation

NOTICES
FBI Criminal Justice Information Services Division User Fee Schedule, 45535

Federal Communications Commission

PROPOSED RULES
Petitions for Reconsideration and Clarification of Action in Rulemaking Proceeding, 45447–45448
NOTICES
Meetings:
  Open Commission Meeting, 45497–45498

Federal Election Commission

NOTICES
Meetings; Sunshine Act, 45498

Federal Emergency Management Agency

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Application for Surplus Federal Real Property Public Benefit Conveyance and BRAC Program for Emergency Management Use, 45518–45519
  Community Rating System Program—Application Worksheets and Commentary, 45517–45518
Disaster Declarations:
  Mississippi; Amendment No. 7, 45517
  Texas; Amendment No. 3, 45519–45520
  West Virginia; Amendment No. 3, 45516
  West Virginia; Amendment No. 5, 45518
Major Disaster Declarations:
  Texas; Amendment No. 5, 45520
  Texas; Amendment No. 6, 45516
  West Virginia; Amendment No. 2, 45520
  West Virginia; Amendment No. 4, 45517
Meetings:
  Board of Visitors for the National Fire Academy, 45515–45516

Federal Energy Regulatory Commission

NOTICES
Applications:
  Grand River Dam Authority, 45461–45462
  Northern Natural Gas Co., 45469–45470
Applications for Certificate of Public Convenience and Necessity:
  TransCameron Pipeline, LLC, 45473
Certificates of Public Convenience and Necessity:
  National Fuel Gas Supply Corp., 45467–45468
  Tennessee Gas Pipeline Co., LLC, 45466
Combined Filings, 45464–45471, 45473–45474
Environmental Impact Statements; Availability, etc.:
  NEXUS Gas Transmission, LLC, Texas Eastern Transmission, LP, et al., NEXUS Gas Transmission Project and Texas Eastern Appalachian Lease Project, 45471–45472
  Swan Lake North Hydro LLC, 45462–45464
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
  Apple Energy LLC, 45464
Meetings:
  PJM Interconnection, LLC (PJM), 45474
  Tribal Consultation; Grand River Dam Authority, 45468

Federal Trade Commission

NOTICES
Proposed Consent Agreements:
  Ball Corporation and Rexam PLC, 45498–45501

Fish and Wildlife Service

PROPOSED RULES
2016-2017 Refuge-Specific Hunting and Sport Fishing, 45790–45830

Food and Drug Administration

RULES
Amendments to Registration of Food Facilities, 45912–45954
Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972; Technical Amendment, 45409
NOTICES
Determinations That Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness:
  PARAFON FORTE DSC (Chlorzoxazone) Tablets, 500 Milligrams, 45507
Foods and Veterinary Medicine Program's Strategic Plan for Fiscal Years 2016–2025, 45507–45509
Guidance for Industry:
  Bacterial Vaginosis: Developing Drugs for Treatment, 45509–45510

Food Safety and Inspection Service

NOTICES
Establishment-Specific Data Release Strategic Plan, 45451–45455

General Services Administration

RULES
Federal Acquisition Regulations:
  Federal Acquisition Circular 2005–89; Small Entity Compliance Guide, 45868–45869
  Federal Acquisition Circular 2005–89; Introduction, 45832–45833
  FPI Blanket Waiver Threshold, 45854–45855
  OMB Circular Citation Update, 45852–45854
  Revision to Standard Forms for Bonds, 45855–45866
  Small Business Subcontracting Improvements, 45833–45851
  Technical Amendments, 45866–45868
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Right of First Refusal of Employment, 45502

Health and Human Services Department

See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Blockchain and its Emerging Role in Health IT and Health-related Research; Requirements and Registration; Amendment, 45510–45511

Homeland Security Department

See Coast Guard
See Federal Emergency Management Agency
See U.S. Customs and Border Protection
NOTICES
Privacy Act; Systems of Records, 45520–45527

Interior Department

See Fish and Wildlife Service
See National Park Service
See Reclamation Bureau
See Surface Mining Reclamation and Enforcement Office
NOTICES
Privacy Act; Systems of Records, 45527–45530

Internal Revenue Service

RULES
Participation of a Person Described in Section 6103(n) in a Summons Interview Under the Internal Revenue Code, 45409–45414

International Trade Administration

NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
  Cold-Rolled Steel Flat Products from Japan and the People's Republic of China, 45956–45960
  Cold-Rolled Steel Flat Products from the People's Republic of China, 45960–45962
  Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China, 45455–45458

International Trade Commission

NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
  Ammonium Sulfate from China, 45533–45534

Justice Department

See Alcohol, Tobacco, Firearms, and Explosives Bureau
See Federal Bureau of Investigation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Survey of State Criminal Investigative Agencies on Law Enforcement Use of Force, 45542–45543
Justice for United States Victims of State Sponsored Terrorism Act, 45535–45539
Privacy Act; Systems of Records, 45539–45541
Proposed Consent Decrees, 45541–45542
Revised Federal Advisory Committee Work Products, 45541

Labor Department

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Certification by School Official, 45543

National Aeronautics and Space Administration

RULES
Federal Acquisition Regulations:
  Federal Acquisition Circular 2005–89; Small Entity Compliance Guide, 45868–45869
  Federal Acquisition Circular 2005–89; Introduction, 45832–45833
  FPI Blanket Waiver Threshold, 45854–45855
  OMB Circular Citation Update, 45852–45854
  Revision to Standard Forms for Bonds, 45855–45866
  Small Business Subcontracting Improvements, 45833–45851
  Technical Amendments, 45866–45868
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Right of First Refusal of Employment, 45502

National Credit Union Administration

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Federal Credit Union Bylaws, 45544

National Institutes of Health

NOTICES
Meetings:
  Center for Scientific Review, 45512–45513
  National Human Genome Research Institute, 45512, 45514
  National Institute of General Medical Sciences, 45513
  Office of the Director, National Institutes of Health, 45513

National Oceanic and Atmospheric Administration

RULES
Fisheries of the Exclusive Economic Zone Off Alaska:
  Gulf of Alaska Pacific Halibut Prohibited Species Catch Limits for the Trawl Deep-water and Shallow-water Fishery Categories; Reapportionment, 45423–45424
NOTICES
Applications for Exempted Fishing Permits, 45459–45460

Fisheries of the Exclusive Economic Zone Off Alaska:
  Bering Sea and Aleutian Islands Crab Rationalization Cost Recovery Program, 45458–45459
Meetings:
  Science Advisory Board, 45460–45461

National Park Service
NOTICES

Inventory Completions:
  Federal Bureau of Investigation, Indianapolis Field Office, Indianapolis, IN, 45531–45532
  University of Alabama Museums, Tuscaloosa, AL, 45532–45533

Postal Regulatory Commission
NOTICES

New Postal Products, 45544–45545

Postal Service
NOTICES

Product Changes:
  Priority Mail and First-Class Package Service Negotiated Service Agreement, 45545
  Priority Mail Express Negotiated Service Agreement, 45545–45546

Railroad Retirement Board
NOTICES

Meetings; Sunshine Act, 45546

Reclamation Bureau
NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 45533

Securities and Exchange Commission
NOTICES

Self-Regulatory Organizations; Proposed Rule Changes:
  Bats BZX Exchange, Inc., 45546–45573
  Miami International Securities Exchange, LLC, 45578–45580
  New York Stock Exchange LLC, 45580–45589
  NYSE Arca, Inc., 45573–45575, 45577–45578, 45590–45591
  NYSE MKT LLC, 45575–45577

Small Business Administration
NOTICES

Conflict of Interest Exemptions:
  Boathouse Capital II, LP, 45591

State Department
NOTICES

Certification Pursuant to the Department of State, Foreign Operations, and Related Programs Appropriations Act, 45593
Designations as Specially Designated Global Terrorists:
  Aslan Avgazarovich, aka Aslan Byutukayev, aka Aslan Byutukaev, aka Emir Khamzat, et al., 45593
  Ayrat Nasimovich Vakhitov, aka Aiat Nasimovich Vahitov, aka Airat Vakhitov, aka Aryat Vakhitov, et al., 45594
Presidential Permit Applications:
  National Interest Determination for NuStar Logistics, LP, 45592–45594
  NuStar Logistics, LP, 45592

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES

Indiana Abandoned Mine Land Reclamation Plan, 45425–45426
Kansas Abandoned Mine Land Reclamation Plan, 45426–45428

Surface Transportation Board
NOTICES

Acquisition and Operation Exemptions:
  Central Texas and Colorado River Railway, LLC, Line of Heart of Texas Railroad, LP, 45596
Acquisition of Control Exemptions:
  Omnitrax Holdings Combined, Inc., Alabama and Tennessee River Railway, LLC, et al., 45594–45596
Continuances in Control Exemptions:
  OmniTRAX Holdings Combined, Inc., Central Texas & Colorado River Railway, LLC, 45596–45597

Transportation Department
See Federal Aviation Administration

Treasury Department
See Internal Revenue Service
NOTICES

Meetings:
  Debt Management Advisory Committee, 45597

U.S. Customs and Border Protection
NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Declaration of Owner and Declaration of Consignee when Entry is made by an Agent, 45514–45515

Veterans Affairs Department
NOTICES

Privacy Act; Systems of Records, 45597–45602

Separate Parts In This Issue

Part II

Health and Human Services Department, Centers for Medicare & Medicaid Services, 45604–45788

Part III

Interior Department, Fish and Wildlife Service, 45790–45830

Part IV

Defense Department, 45832–45869
General Services Administration, 45832–45869
National Aeronautics and Space Administration, 45832–45869

Part V

Transportation Department, Federal Aviation Administration, 45872–45909

Part VI

Health and Human Services Department, Food and Drug Administration, 45912–45954

Part VII

Commerce Department, International Trade Administration, 45956–45962

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
319.....45387

10 CFR
429.....45387
430.....45387

14 CFR
25.....45405
71.....45407
Proposed Rules:
139.....45872

21 CFR
1.....45912
14.....45409
20.....45409

26 CFR
301.....45409

30 CFR
Proposed Rules:
914.....45425
916.....45426

33 CFR
165.....45414
Proposed Rules:
110.....45428

40 CFR
9.....45416
52 (3 documents).....45417, 45419, 45421
721.....45416
Proposed Rules:
52 (3 documents).....45428, 45438, 45447

42 CFR
Proposed Rules:
416.....45604
419.....45604
482.....45604
486.....45604
488.....45604
495.....45604

47 CFR
Proposed Rules:
54.....45447

48 CFR
Ch. 1 (2 documents).....45832, 45868
1.....45833
2 (2 documents).....45833, 45852
4.....45866
8.....45854
15 (2 documents).....45833, 45852
16.....45852
19.....45833
31.....45852
42.....45852
52 (3 documents).....45833, 45852, 45866
53.....45855

50 CFR
679.....45423
Proposed Rules:
32.....45790

Rules and Regulations

Federal Register
Vol. 81, No. 135
Thursday, July 14, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2006–0121]

RIN 0579–AC19

Importation of Mangoes From India; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: We are amending the regulations regarding the importation of mangoes from India to further clarify our requirements regarding inspection of the mangoes. A previous technical amendment amended the regulations to allow mangoes treated with irradiation in the United States to be inspected by the national plant protection organization (NPPO) of India in India, and subsequently by the Animal and Plant Health Inspection Service (APHIS) at the port of entry within the United States, rather than being jointly inspected by APHIS and the NPPO in India in all cases. However, in that technical amendment, we neglected to also remove two references to preclearance inspections within India. This document corrects that error.

DATES: Effective July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Russo, Director, Imports, Regulations, and Manuals, APHIS–PPQ Unit 133, Riverdale, MD 20737–1236; (301) 851–2159.

SUPPLEMENTARY INFORMATION: In a final rule[1] published in the **Federal Register** on July 20, 2012 (77 FR 42621–42625, Docket No. APHIS–2009–0100), and effective on August 20, 2012, we amended the regulations in 7 CFR 319.56–46 to allow for irradiation treatment of mangoes from India upon arrival in the mainland United States rather than just at the point of origin.

In a technical amendment[2] published in the **Federal Register** on September 21, 2012 (77 FR 58470–58471, Docket No. APHIS–2009–0100), we amended paragraph (c) of § 319.56–46, which contains inspection requirements for mangoes from India, to allow mangoes intended for irradiation treatment within the United States to be inspected by the national plant protection organization (NPPO) of India prior to shipment to the United States, and subsequently to be inspected by an inspector upon arrival at the port of entry in the United States. Prior to that technical amendment, paragraph (c) had required a joint preclearance inspection in India for all mangoes intended for export to the United States.

In that technical amendment, however, we neglected to also amend paragraphs (d) and (e)(2) of § 319.56–46, which together required consignments of mangoes to be inspected during preclearance activities and accompanied by a phytosanitary certificate with an additional declaration that the mangoes were inspected during preclearance activities and found free of *Cytosphaera mangiferae, Macrophoma mangiferae,* and *Xanthomonas campestri* pv. *mangiferaeindicae.*

Because we did not amend these requirements to remove references to preclearance activities, there has continued to be confusion among stakeholders regarding whether preclearance inspections are required for mangoes from India intended for irradiation in the United States. As noted in the previous technical amendment, however, we consider preclearance inspections, which are jointly conducted by the Animal and Plant Health Inspection Service and the NPPO of India, to be necessary only when irradiation will take place in India. If the mangoes will be irradiated in the United States, we require the mangoes to be inspected in the United States prior to this treatment. Accordingly, it is more useful and cost effective for the NPPO to initially inspect the mangoes in India, and for us to subsequently inspect the mangoes at the port of entry into the United States. As a result, we are amending paragraphs (d) and (e)(2) of § 319.56–46 to remove their references to preclearance activities.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 319.56–46 [Amended]

■ 2. In § 319.56–46, paragraphs (d) and (e)(2) are amended by removing the words "during preclearance activities".

Done in Washington, DC, this 8th day of July 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–16702 Filed 7–13–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket No. EERE–2011–BT–CE–0077]

RIN 1904–AC68

Energy Conservation Program: Enforcement of Regional Standards for Central Air Conditioners

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: In this final rule, DOE is adopting provisions pertaining to the enforcement of regional standards for central air conditioners, which were largely based on recommendations from a negotiated rulemaking term sheet. On November 19, 2015, the U.S.

---

[1] To view the final rule and related documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0100.*

[2] To view the technical amendment, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0100.*

Department of Energy (DOE) issued a notice of proposed rulemaking (NOPR) to adopt requirements related to the enforcement of regional standards for central air conditioners, as authorized by the Energy Policy and Conservation Act (EPCA) of 1975. That proposed rulemaking serves as the basis for this final rule. The provisions adopted in this final rule will aid the Department in enforcing its energy conservation standards for central air conditioners that are regionally based.

DATES: The effective date of this rule is August 15, 2016.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *regulations.gov*. All documents in the docket are listed in the *regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket Web page can be found at: *https://www.regulations.gov/#!docketDetail;D=EERE-2011-BT-CE-0077*. This Web page will contain a link to this final rule on the *regulations.gov* site. The *regulations.gov* Web page will contain simple instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact the Appliance and Equipment Standards staff at (202) 586–6636 or by email: *central_air_conditioners_and_heat_pumps@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT:

Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *Ashley.Armstrong@ee.doe.gov*.

Ms. Laura Barhydt, U.S. Department of Energy, Office of the General Counsel, GC–32, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–5772. Email: *Laura.Barhydt@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Authority and Background
  A. Authority
  B. Background
II. Discussion
  A. General Comments
  B. Clarifications to Regional Standards
  C. Private Labelers
  D. Definitions
  E. Public Awareness
  F. Reporting
  G. Proactive Investigation
  H. Records Retention and Requests
  I. Violations and Routine Violations
  J. Remediation
  K. Manufacturer Liability
  L. Impact of Regional Enforcement on National Impacts Analysis
III. Procedural Issues and Regulatory Review
IV. Approval of the Office of the Secretary

I. Authority and Background

A. Authority

Title III of the Energy Policy and Conservation Act of 1975, as amended ("EPCA" or, in context, "the Act") sets forth a variety of provisions designed to improve energy efficiency.[1] Part A of Title III[2] (42 U.S.C. 6291–6309) establishes the "Energy Conservation Program for Consumer Products Other Than Automobiles." These consumer products include central air conditioners, which are the subject of this rule.

Under EPCA, this program consists essentially of four parts: (1) Testing; (2) labeling; (3) Federal energy conservation standards; and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling consumer products, and DOE implements the remainder of the program.

Pursuant to EPCA, any new or amended energy conservation standards for covered consumer products must be designed to achieve the maximum improvement in energy efficiency that are technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) The Energy Independence and Security Act of 2007 (EISA 2007) amended EPCA to require that DOE consider regional standards for certain products if the regional standards can save significantly more energy than a national standard and are economically justified. (42 U.S.C. 6295(o)(6)(A)) Under EPCA, DOE is authorized to establish up to two additional regional standards for central air conditioners and heat pumps. (42 U.S.C. 6295(o)(6)(B)(ii)) DOE was required to initiate an enforcement rulemaking after DOE issued a final rule that establishes a regional standard (42 U.S.C. 6295(o)(6)(G)(ii)(I)) and issue a final rule. (42 U.S.C. 6295(o)(6)(G)(ii)(III))

B. Background

On June 27, 2011, DOE promulgated a Direct Final Rule (June 2011 DFR) that, among other things, established regional standards for central air conditioners. 76 FR 37408. Under the June 2011 DFR, after January 1, 2015, split-system central air conditioners in the Southeast[3] and Southwest[4] must have a Seasonal Energy Efficiency Ratio (SEER) not less than 14. 76 FR at 37547. In addition, the DFR stated that in the Southwest, split-systems with rated cooling capacities less than 45,000 Btu/h must have an Energy Efficiency Ratio (EER) not less than 12.2, split-systems with rated cooling capacities equal to or greater than 45,000 Btu/h must have an EER not less than 11.7, and single-package systems must not have an EER less than 11.0. *Id.* DOE subsequently published a notice of effective date and compliance date for the June 2011 DFR on October 31, 2011, setting a standards compliance date for central air conditioners and heat pumps of January 1, 2015. 76 FR 67037.

As required by EPCA, DOE initiated an enforcement rulemaking by publishing a notice of data availability (NODA) in the **Federal Register** that proposed three approaches to enforcing regional standards for central air conditioners. 76 FR 76328 (December 7, 2011). DOE received numerous comments expressing a wide range of views in response to this NODA. Consequently, on June 13, 2014, DOE published a notice of intent to form a working group to negotiate regulations for the enforcement of regional standards for central air conditioners and requested nominations from parties interested in serving as members of the Working Group. 79 FR 33870. On July 16, 2014, the Department published a notice of membership announcing the eighteen nominations that were selected to serve as members of the Working Group, in addition to two members from Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC), and one DOE representative. 79 FR 41456. The members of the Working Group were selected by ASRAC to ensure a broad and balanced array of stakeholder interests and expertise, and included efficiency advocates, utility representatives, and manufacturers, contractors, and distributors of central air conditioners. *Id.*

---

[1] All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Public Law 114–11 (Apr. 30, 2015).

[2] For editorial reasons, Part B was redesignated as Part A upon incorporation into the U.S. Code (42 U.S.C. 6291–6309, as codified).

[3] The southeast region includes states with a hot-humid climate. These states are Alabama, Arkansas, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia, and in the District of Columbia. 76 FR at 37547.

[4] The southwest region includes states with a hot-dry climate. These states are Arizona, California, Nevada, and New Mexico. 76 FR at 37547.

Between August 13, 2014, and October 24, 2014, the Working Group held fourteen public meetings in Washington, DC, primarily at the DOE headquarters.[5] Thirty-seven interested parties, including members of the Working Group, attended the various meetings. For more details see the Working Group meeting transcripts.[6]

The Working Group submitted a final report to ASRAC on October 24, 2014, summarizing the group's recommendations for DOE's rule for enforcement of regional standards for central air conditioners. Working Group Recommendations, No. 70.[7] The recommendations included a statement that the nongovernmental participants conditionally approved the recommendations contingent upon the issuance of final guidance (see No. 89 and No. 90 for the draft versions) consistent with the understanding of the Working Group as set forth in these recommendations. Working Group Recommendations, No. 70 at 37. ASRAC subsequently voted to approve these recommendations on December 1, 2014. (ASRAC Meeting Transcript, No. 73 at pp. 42–43).

DOE presented the Working Group's recommendations in separate rulemakings. DOE proposed regulatory changes related to unit selection and testing requirements in a supplemental notice of proposed rulemaking for CAC test procedures (November 2015 CAC TP SNOPR) on November 9, 2015 and finalized them on June 8, 2016 (June 2016 CAC TP final rule. 80 FR 69277, 81 FR 36992. DOE presented the Working Group's recommendations for enforcement of regional standards for central air conditioners in a NOPR published on November 19, 2015 (November 2015 NOPR). 80 FR 72373. DOE is now finalizing them in this final rule.

II. Discussion

As previously stated, DOE proposed the Working Group's recommendations for enforcement of regional standards for central air conditioners in the November 2015 NOPR. See 80 FR 72373. In response to the November 2015 NOPR, DOE received comments from 11 interested parties including manufacturers, trade associations, advocacy groups, and a utility association. Interested parties provided comments on a range of issues, including those DOE identified in the November 2015 NOPR, as well as issues related to the enforcement procedure changes. The issues on which DOE received comments, as well as DOE's responses to those comments and the resulting changes to the enforcement proposals presented in the November 2015 NOPR, are discussed in the subsequent sections.[8]

TABLE II.1—STAKEHOLDERS THAT SUBMITTED COMMENTS ON THE NOPR

Name	Acronym	Organization type
Advanced Distributor Products, LLC	ADP	Manufacturer.
Air-Conditioning, Heating and Refrigeration Institute	AHRI	Trade Association.
California Investor Owned Utilities	CA IOUs	Utility Association.
Carrier Corporation	Carrier	Manufacturer.
Earthjustice	Earthjustice	Energy Efficiency Advocacy Group.
Heating, Air-conditioning, and Refrigeration Distributors International.	HARDI	Trade Association.
Ingersoll Rand Residential Solutions	Ingersoll Rand	Manufacturer.
Lennox International, Inc.	Lennox	Manufacturer.
Natural Resources Defense Council	NRDC	Energy Efficiency Advocacy Group.
Appliance Standards Awareness Project	ASAP	Energy Efficiency Advocacy Group.
Rheem Manufacturing Company	Rheem	Manufacturer.

A. General Comments

DOE received several general comments in response to the November 2015 NOPR. NRDC, Earthjustice, and ASAP support the proposal for enforcement of regional standards for central air conditioners. (NRDC, Earthjustice, and ASAP, No. 96 at p. 1) Ingersoll Rand commented that they support AHRI's comments. (Ingersoll Rand, No. No. 100 at p. 2)

In addition, DOE received some comments pertaining to the effective dates, enforcement policies, and other aspects of the proposed rule. Rheem commented that the updates to § 430.32 that are shown beginning on the NOPR page 72389 clarify the effective dates to (1) include the agreements on the sell through period; and (2) the off-mode power requirements for which there is currently no finalized test procedure. 80 FR 72373, 72389 (Nov. 19, 2015). Rheem suggested that the **Federal Register** should include a complete, accurate, and transparent account of the effective dates and enforcement policies associated with each for both current and historical references. (Rheem, No. 98 at p. 1)

In response, DOE clarifies that the updates to § 430.32 that were proposed in the NOPR did not change the effective compliance and installation dates for the regional standard. DOE proposed to remove the former energy conservation standards that were surpassed by the current standard levels, and DOE added language related to the Working Group's recommendation that units rated below the regional standard by the OEM cannot be installed in such region. 80 FR 72373, 72389 (Nov. 19, 2015). DOE published a notice of effective date and compliance date for the June 2011 DFR on October 31, 2011, which detailed the compliance dates for central air conditioners and heat pumps standards. 76 FR 67037. As Rheem indicated, DOE issued enforcement guidance stating that DOE will not seek civil penalties for violations of the regional standards applicable to central air conditioners that occur prior to July 1, 2016, provided that the violations are related to the distribution in commerce of units manufactured prior to January 1, 2015.[9] This enforcement guidance does not amend the compliance dates of the for central air conditioners and heat pumps standards, but rather is an exercise of DOE's discretion by providing a sell through period for central air conditioners impacted by regional standards.

---

[5] The Working Group met on August 13, 2014; August 14, 2014; August 26, 2014; August 27, 2014; August 28, 2014; September 3, 2014; September 4, 2014; September 24, 2014; September 25, 2014; October 1, 2014; October 2, 2014; October 15, 2014; October 16, 2014; and October 24, 2014. Due to space conflicts at DOE, the August 27th meeting took place at ACEEE's office in Washington, DC.

[6] Docket Folder, Energy Conservation Program: Enforcement of Regional Standards for Residential Furnaces and Central Air Conditioners and Heat Pumps, *http://www.regulations.gov/#!docketDetail;D=EERE-2011-BT-CE-0077.*

[7] A notation in this form provides a reference for information that is in the docket for this rulemaking (Docket No. EERE–2011–BT–CE–0077), which is maintained at *www.regulations.gov*. This notation indicates that the statement preceding the reference is from document number 70 in the docket.

[8] A full set of comments can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2011-BT-CE-0077.*

In regard to the off-mode power consumption standards, Carrier commented that, while it has no issue with the specific level of watt consumption requirements, it has issues with the retroactive implementation date of January 1, 2015. Carrier cited the DOE Enforcement Policy Statement of July 8, 2014, which stated ". . . until 180 days following publication of final rule establishing a test method. . . ."[10] Based on this enforcement policy, Carrier believed DOE should modify the compliance date in the CFR to at least 180 days following the publishing of the final test procedure, and requested that DOE consider a 360 day implementation to allow for testing of highest sales volume tested combination. (Carrier, No. 97 at pp. 5–6)

In response to Carrier and Rheem's comments regarding off-mode power consumption, DOE established the effective date and compliance date for the June 2011 DFR in a separate rule published on October 31, 2011. 76 FR 67037. As Carrier stated, DOE's enforcement policy statement for off mode standards for central air conditioners and heat pumps is currently applicable to off-mode standards for central air conditioners and heat pumps, and will be until the dates mentioned in the policy statement.[11] Specifically, DOE finalized test procedures for off-mode standards in a final rule published on June 8, 2016. 81 FR 36992. In accordance with the enforcement policy statement, DOE will not assert civil penalty authority for violation of the off mode standard specified at 10 CFR 430.32(c)(6) until December 5, 2016, which is 180 days after the publication of the final rule. This enforcement policy does not change the legal requirements or the compliance date. Therefore, manufacturers will be required to comply with the July 8, 2016 for off-mode testing.

HARDI requested in its comments that DOE effectively communicate all aspects of this standard and its subsequent enforcement to state governments, as some states may enact policies that preempt federal policy. (HARDI, No. 94 at p. 2) As recommended by the Working Group, DOE is promoting public awareness of the regional standards and regional enforcement policy by establishing a Web site, hosting a public meeting, and publishing informative literature on its Web site. DOE's Web page for regional standards can be found at *http://www.energy.gov/gc/regional-standards-enforcement*. This Web page includes a brochure for installers and purchasers of central air conditioners. DOE has also been answering questions from state and local governments regarding both the regional standards and DOE's enforcement policy and will continue to do so.

B. Clarifications to Regional Standards

As previously mentioned, DOE adopted regional standards for central air conditioners in its June 2011 DFR. That rule established regional standards for split-system central air conditioners and single-package central air conditioners. 10 CFR 430.32(c).

A split-system central air conditioner is a kind of air conditioner that has one or more of its major assemblies separated from the others. Typically, the air conditioner has a condensing unit ("outdoor unit") that is separate from the evaporator coil and/or blower ("indoor unit"). Accordingly, a split-system condensing unit is often sold separately from the indoor unit and may be matched with several different models of indoor units and/or blowers. For this reason, a condensing unit could achieve a 14 SEER or above if it is paired with certain indoor units and/or blowers and could perform below 14 SEER when paired with other indoor units and/or blowers. 80 FR 72373 (November 19, 2015).

During their meetings, the Working Group suggested the regional standards required clarification because a particular condensing unit may have a range of efficiency ratings when paired with various indoor evaporator coils and/or blowers. The Working Group provided the following four recommendations to clarify the regional standards: (1) The least efficient rated combination for a specified model of condensing unit must be 14 SEER for models installed in the Southeast and Southwest regions; (2) the least efficient rated combination for a specified model of condensing unit must meet the minimum EER for models installed in the Southwest region; (3) any condensing unit model that has a certified combination that is below the regional standard(s) cannot be installed in that region; and (4) a condensing unit model certified below a regional standard by the original equipment manufacturer cannot be installed in a region subject to a regional standard(s) even with an independent coil manufacturer's indoor coil or air handler combination that may have a certified rating meeting the applicable regional standard(s). Working Group Recommendations, No. 70 at 4. In the November 2015 NOPR, DOE proposed to adopt these recommendations and requested comment on these recommendations. 80 FR 72373, 72375 (November 19, 2015).

Interested parties submitted comments on the proposed clarification to the regional standards. In their comments, ADP and Lennox supported the clarifications discussed in the NOPR. Further, ADP and Lennox recommended these clarifications be used to provide consistent language in the central air conditioner test procedure rulemaking that are based on basic models. (ADP, No. 93 at p. 1; Lennox, No. 95 at p. 2) Rheem also agreed with the four clarifications to the regional standards discussed in the November 2015 NOPR. In its comments, Rheem stated it could also support the new alternative proposed by DOE concerning combinations permitted to be certified, if the alternative would not impose additional testing costs and burdens. (Rheem, No. 98 at p. 2) CA IOUs supported DOE's conclusion that split-system condensing units should be rated with their lowest performing evaporator combination. (CA IOUs, No. 99 at p. 2)

Alternatively, Carrier and AHRI commented that the approach proposed in the November 2015 NOPR was preferable to the approach proposed in the CAC test procedure SNOPR. Carrier and AHRI explained that the SNOPR approach would mean that an ICM (independent coil manufacturer) could have a CAC basic model meeting the Southeast or Southwest Regional Standard even when the outdoor unit manufacturer certified the condensing unit paired with the ICMs indoor unit below 14 SEER. (Carrier, No. 97 at p. 2; AHRI, No. 101 at p.3)

DOE's proposal in the CAC test procedure SNOPR was to make clear that it is not permissible for an outdoor unit that is certified as meeting a regional standard (*i.e.,* the OUM (outdoor unit manufacturer) does not make any representation below the regional standard for that outdoor unit) to be certified in a combination that does not meet the regional standard. That includes both certifications by an OUM and an ICM. DOE has finalized that approach in the CAC test procedure final rule.[12]

---

[9] Enforcement Policy Statement: Regional Standards Sell-Through. The full enforcement policy can be found at: *http://www.energy.gov/gc/downloads/enforcement-policy-regional-standards-sell-through.*

[10] Enforcement Policy Statement: Off Mode Standards for Central Air Conditioners and Central Air Conditioning Heat Pumps. The full enforcement policy can be found at: *http://www.energy.gov/gc/downloads/enforcement-policy-statement-mode-standards-cachp.*

[11] *Id.*

Nonetheless, DOE understands AHRI and Carrier to be concerned that, if an ICM certifies a combination in violation of the regulations, there is no separate prohibition against installing that combination. DOE had proposed in the November 2015 NOPR to include the following language at 10 CFR 430.32(c)(3)–(4): "An outdoor unit model certified below 14 SEER by the outdoor unit manufacturer cannot be installed in this region even with an independent coil manufacturer's indoor unit that may have a certified rating at or above 14 SEER." For consistency between its CAC TP and regional standards, DOE clarified in the June 2016 CAC TP final rule at 10 CFR 429.16(a)(3)(A) specific limitations for tested combinations subject to regional standards ("a basic model may only be certified as compliant with a regional standard if all individual combinations within that basic model meet the regional standard for which it is certified . . . [and] an ICM cannot certify a basic model containing a representative value that is more efficient than any combination certified by an OUM containing the same outdoor unit"). In this final rule, DOE is adopting complementary language at 10 CFR 430.32(c)(3)–(4): "[a]ny outdoor unit model that has a certified combination with a rating below 14 SEER cannot be installed in these States." DOE intends this modified language to prevent any model that is rated below the Southeast or Southwest Regional Standard by the OUM from being installed in those regions. Further, this language maintains the Working Group's clarification that an outdoor unit certified below a regional standard by the original equipment manufacturer cannot be installed in a region subject to a regional standard(s) even with an independent coil manufacturer's indoor coil.

C. Private Labelers

As discussed in the November 2015 NOPR, DOE received questions about the applicability of the regional standards to private labelers, which was an entity not addressed by the Working Group. In response, DOE noted that, although private labelers are liable for distribution in commerce of noncompliant products generally, DOE does not require private labelers to submit certification reports unless the private labeler is also the importer. DOE suggested that it may not be necessary for exactly the same requirements to apply to private labelers. Consequently, DOE requested comment on whether these proposed requirements should be the same for manufacturers and private labelers or whether different requirements should apply. 80 FR 72373.

Commenters generally agreed that the proposed requirements should apply to private labelers in the same way that the requirements apply to manufacturers. Lennox strongly recommended that DOE apply the same enforcement requirements for manufacturers to private labelers of products covered under this rule. (Lennox, No. 95 at p. 2) NRDC, Earthjustice, and ASAP also supported the Department's proposal to treat private labelers the same as manufacturers. (NRDC, Earthjustice, and ASAP, No. 96 at p. 1) Carrier and AHRI commented that if private labelers are importers, then the private labelers should be subject to the same requirements as manufacturers, consistent with DOE's determination elsewhere in the November 2015 NOPR. Carrier and AHRI further stated that, even if private labelers are not importers and the product does not bear the brand, trademark, or other marking of the manufacturer of the product, then the private labeler should still be treated as a manufacturer. (Carrier, No. 97 at p. 4; AHRI, No. 101 at p. 3)

Accordingly, DOE adopts the same requirements for private labelers and manufacturers in this final rule as a result of comments received.

D. Definitions

EPCA prohibits manufacturers from selling to "distributors, contractors, or dealers that routinely violate the regional standards." (42 U.S.C. 6302(a)(6)) In the November 2015 NOPR, DOE proposed definitions for "contractor," "dealer," and "installation of a central air conditioner." Under the November 2015 SNOPR, a "contractor" is a person (other than the manufacturer or distributor) who sells to and/or installs for an end user a central air conditioner subject to regional standards. A "dealer" is a type of contractor, generally with a relationship with one or more specific manufacturers. "Installation of a central air conditioner" means the connection of the refrigerant lines and/or electrical systems to make the central air conditioner operational. 80 FR 72373 (November 19, 2015).

Commenters agreed with the proposed definitions. (ADP, No. 93 at p. 1; Rheem, No. 98 at p. 2; Carrier, No. 97 at p. 3; Lennox, No. 95 at p. 2) Accordingly, DOE adopts the November 2015 NOPR proposed definitions for contractor, dealer, and installation of a central air conditioner in this final rule.

E. Public Awareness

In the November 2015 NOPR, DOE reiterated the Working Group's recommendations related to public awareness. 80 FR 72373, 72376–77 (Nov. 19, 2015). DOE did not receive any comments specific to the Working Groups recommendations on public awareness.

Per the Working Group's recommendation, DOE established a Web page with information on regional standards for CACs that could be referenced by manufacturers, distributors, contractors, and other interested parties. This Web page can be found at *http://www.energy.gov/gc/regional-standards-enforcement.* DOE posted on its regional standards Web page a printable trifold to provide information to consumers and contractors and to answer common questions. All information sources include information, including email links, on how to report suspected violations of the CAC regional standards. DOE encourages manufacturers to provide the information to its distributors, distributors to provide the information to contractors, and contractors to provide this information to purchasers.

The Working Group also recommended that DOE conduct a public presentation (accessible via internet as well as in-person) on regional standards for CACs and the enforcement of such standards in order to educate stakeholders and the public on these regulations. DOE will announce the details for an educational presentation about regional standards soon. (DOE expects that the presentation will be in July 2016.) After the presentation, DOE will post the slides from the presentation to the docket for this rulemaking and on the regional standards Web page.

Finally, the Working Group recommended that CAC manufacturers provide training about regional standards to distributors and contractors/dealers. Distributors and contractors also agreed to conduct their own training on regional standards. The Working Group did not establish specific guidelines for the training. DOE does not have information about whether or to what extent the manufacturers, distributors and contractors have conducted/participated in such training. However, DOE encourages all CAC manufacturers to provide training to their distributors and contractors/dealers as part of their commitment to the Working Group.

---

[12] See the Section III.A.4 of the CAC test procedure final rule at 81 FR 36992 (June 8, 2016).

F. Reporting

The Working Group discussed methods for facilitating the reporting of suspected regional standards violations and recommended that the Department provide multiple pathways for the public to report such information, such as accepting complaints regarding CAC regional standards from an email address and call-in number. The Working Group emphasized the importance that a complainant receive confidential treatment to the maximum extent authorized by law. DOE did not receive any comments specific to the Working Groups recommendations on reporting of suspected regional standards violations.

As discussed in the November 2015 NOPR, the Department accepts reports of suspected violations of the regional central air conditioner standards that are received via email at *EnergyEfficiencyEnforcement@hq.doe.gov* or phone at 202–287–6997. 80 FR 72373, 72377 (Nov. 19, 2015). DOE remains committed to investigating all credible complaints.

G. Proactive Investigation

In addition to responding to reports of noncompliance with the regional standards, the Working Group recommended that the Department consider conducting proactive investigations. Specifically, the Working Group recommended that, if funding is available, DOE consider conducting a survey of homes in any region of the United States to determine if a central air conditioner not in compliance with the regional standards has been installed. DOE, as a member of the Working Group, agreed to consider proactive investigations if funding for such investigations is available, but has not yet conducted such a survey. DOE did not receive any comments specific to the Working Group recommendations on proactive investigations.

H. Records Retention and Requests

In the November 2015 NOPR, DOE proposed to adopt the Working Group's recommended records retention requirements for contractors and dealers, distributors, and manufacturers and private labelers with two modifications. Due to the delay in issuing the NOPR, DOE proposed that distributors be required to retain records beginning July 1, 2016, instead of November 30, 2015. Additionally, DOE proposed to replace the term ''indoor coils or air handlers'' with the term ''indoor unit'' in order to harmonize with the CAC TP supplemental notice of proposed rulemaking (SNOPR). See 80 FR 69278 at 69284. The records retention scheme was proposed as follows:

Beginning 30 days after the issuance of a final rule, a manufacturer must retain:

- For split-system central air conditioner condensing units: The model number, serial number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number);
- For split-system central air conditioner indoor units (not including uncased coils sold as replacement parts): The model number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number); and
- For single-package central air conditioners: The model number, serial number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number).

Beginning July 1, 2016,[13] a distributor must retain:

- For split-system central air conditioner condensing units: The manufacturer, model number, serial number, date the unit was purchased from the manufacturer, party from whom the unit was purchased (including person's name, full address, and phone number), date unit was sold to a dealer or contractor, party to whom the unit was sold (including person's name, full address, and phone number), and, if delivered to the purchaser, the delivery address; and
- For single-package central air conditioners: The manufacturer, model number, serial number, date the unit was purchased from the manufacturer, party from whom the unit was purchased (including person's name, full address, and phone number), date unit was sold to dealer or contractor, party to whom the unit was sold (including person's name, full address, and phone number), and, if delivered to the purchaser, the delivery address.

For all installations in the Southeast and Southwest, beginning 30 days after issuance of a final rule in this rulemaking, contractors must retain:

- For split-system central air conditioner condensing units: The manufacturer name, model number, serial number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number);
- For split-system central air conditioner indoor units (not including uncased coils sold as replacement parts): The manufacturer name, model number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number); and
- For single-package central air conditioners: The manufacturer name, model number, serial number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number).

The Working Group recommended that contractors retain records for 48 months after the date of installation, distributors retain records for 54 months after the date of sale, and manufacturers retain records for 60 months after the date of sale. The Working Group explicitly noted that retaining records allows each entity to archive records as long as the entity does not delete or dispose of the records. The Working Group also clarified that the records retention requirements neither mandate that contractors, distributors, or manufacturers create new forms for the purpose of tracking central air conditioners nor require records to be electronic. DOE proposed in the November 2015 NOPR to adopt these record retention period requirements. See 2013–BT–NOC–0005, No. 30 at 17–18, 80 FR 72373, 72377–78 (Nov. 19, 2015).

Interested parties generally supported the proposed records retention requirements. (ADP, No. 93 at p. 2; CA IOUs, No. 99 at p. 3; Carrier, No. 97 at p. 3; Lennox, No. 95 at p. 2; Rheem, No. 98 at p. 2) HARDI specifically supported DOE's proposal to require record keeping for distributors to take effect on July 1, 2016. (HARDI, No. 94 at p. 1) AHRI noted that DOE's proposed regulatory text for record retention requirements would need to be aligned with the revised date for distributors proposed by DOE (July 1, 2016), instead of the date of November 30, 2015. (AHRI, No. 101 at p. 6)

---

[13] The Working Group originally recommended that distributors retain records beginning on November 30, 2015.

Some commenters noted that the proposed requirements impose additional costs on contractors, dealers, distributors, manufacturers, and private labelers. Carrier noted there would be a cost associated with record retrieval but stated it supported the proposed requirements. (Carrier, No. 97 at p. 3) Although HARDI commented that the cost to alter inventory accounting systems and modify processes for the recordkeeping requirements is significant, it also noted that it was part Working Group and voted in support of these requirements. (HARDI, No. 94 at p. 1) In response, DOE understands that there is an additional cost. However, as HARDI commented, DOE notes that the Working Group was fully aware of the additional cost when it voted to support these provisions and the Working Group attempted to minimize the cost to the greatest extent possible.

Some commenters disagreed with DOE's proposed use of the term "indoor unit" with respect to the record retention requirements for split-system air conditioners. Because DOE proposed a definition for "indoor unit" that does not include casing or expansion device, AHRI expressed concern that the uncased coil would no longer be within the scope of regulation. At the same time, AHRI supported the current status of service coils as "not rated" and would like DOE to make it clear that they will not be rated in the future. To aid DOE in addressing this problem, AHRI recommended definitions for the terms uncased coil, cased coil, service coil, air handler, blower coil, coil-only, and indoor unit.[14] (AHRI, No. 101 at pp. 2–3)

ADP and Lennox commented that DOE needed a clear definition of "uncased coils sold as replacement parts" that are not required to be recorded versus uncased coils sold as a part of a new CAC installation that are required to be recorded. (ADP, No. 93 at p. 2; Lennox, No. 95 at p. 2) Rheem also mentioned that that comments it submitted in response to the test procedure SNOPR requested that DOE ensure that "service coils" are not a covered product and that consistent terminologies are used to describe air handlers, blower coils, coil-only and indoor units.

DOE appreciates the suggested definitions and clarifications suggested by AHRI, Lennox, ADP, and Rheem. To address these comments and the comments received in response to the CAC TP SNOPR, DOE adopted definitions of the terms blower coil indoor unit, blower coil system, cased coil, coil-only indoor unit, coil-only system, indoor unit, service coil, and uncased coil. For more details on these definitions see the CAC test procedure final rule at 81 FR 36992 (June 8, 2016). In addition, as requested by Rheem, ADP, and Lennox, DOE is not requiring manufacturers, distributors, or installers to retain records for service coils.

Therefore, in this final rule, DOE adopts the record retention requirements recommended by the Working Group with the two modifications proposed in the November 2015 NOPR. 80 FR 72373, 72377–72378 (Nov. 19 2015).

In the November 2015 NOPR, DOE defined a threshold for records requests and proposed a timeframe for responding to such requests. Specifically, DOE proposed that DOE must have reasonable belief that a violation has occurred to request records specific to an on-going investigation of a violation of central air conditioner regional standards. Upon request, the manufacturer, private labeler, distributor, dealer, or contractor must provide to DOE the relevant records within 30 calendar days of the request. DOE may grant additional time for records production at its discretion. 80 FR 72373, 72378 (November 19, 2015).

DOE requested comments from interested parties on the proposed threshold for a records request and proposed a timeframe for responding to such requests in its November 2015 NOPR. Commenters generally agreed with the proposed threshold and timeframe. (ADP, No. 92 at p. 2; Rheem, No. 98 at p. 2; Lennox, No. 95 at p. 3) Some commenters agreed with the proposed threshold and timeframe but emphasized the need for discretion to grant additional time for production of records. Carrier agreed with the threshold for records request and the proposed 30-day timeframe, as long as DOE uses discretion to grant additional time for production of records as long as the entity is making a good-faith effort. (Carrier, No. 93 at p. 3) HARDI stated that it believes the 30-day threshold is sufficient, but expressed the view that DOE should allow for extra time upon request, as many small entities have little or no experience in complying with such a request. (HARDI, No. 94 at p. 2)

To address Carrier's and HARDI's concerns, DOE reiterates that it may grant additional time for production of records as long as the affected entity makes a good faith effort to respond to the records request. As explained in the November 2015 NOPR, to receive this extra time, the entity, after working to gather the records within the 30 days, must provide DOE all the records gathered and a written explanation for the need for additional time including the requested date for completing the records request. 80 FR at 72377. DOE also notes that both Carrier and HARDI were part of the negotiated rulemaking and agreed to these terms as part of the Working Group.

In this final rule, DOE adopts the proposed threshold for records requests and the timeline to respond to such requests.

I. Violations and Routine Violations

In the November 2015 NOPR, DOE proposed to adopt the Working Group's recommendations on regional standards violations for distributors, contractors or dealers in order to clarify the prohibition on manufacturers knowingly selling to such entities that are routine violators. (42 U.S.C. 6302(a)(6), 10 CFR 430.102(a)(10))

For a distributor, the Working Group agreed that it would be a violation to knowingly sell a product to a contractor or dealer with knowledge that the entity will sell and/or install the product in violation of any regional standard applicable to the product. Additionally, it would be a violation for a distributor to knowingly sell a product to a contractor or dealer with knowledge that the entity routinely violates any regional standard applicable to the product. For contractors, the Working Group agreed it would be a violation to knowingly sell to and/or install for an end user a central air conditioner subject to regional standards with knowledge that such product would be installed in violation of any regional standard applicable to the product. 80 FR 72373 (November 19, 2015).

To further clarify what constituted an installation of a central air conditioner in violation of an applicable regional standard, the Working Group agreed that:

(1) A person cannot install a complete central air conditioner system—meaning the condensing unit and evaporator coil and/or blower—unless it has been certified as a complete system that meets the applicable standard. A previously discontinued combination may be installed as long as the combination was previously validly certified to the Department as compliant with the applicable regional standard and the combination was not discontinued because it was found to be noncompliant with the applicable standard(s);

---

[14] A full description of the definitions proposed by AHRI can be found in AHRI's comment at *http://www.regulations.gov/#!docketDetail;D=EERE-2011-BT-CE-0077.*

(2) A person cannot install a replacement condensing unit unless it is certified as part of a combination that meets the applicable standard; and

(3) A person cannot install a condensing unit that has a certified combination with a rating that is less than the applicable regional standard.

Interested parties submitted comments on the proposed violations for distributors, contractors, and dealers. Commenters generally agreed with the proposed violations. (ADP, No. 93 at p. 2; CA IOUs, No. 99 at p. 2; Lennox, No. 95 at p. 3; Rheem, No. 98 at p. 3) Therefore, DOE adopts these violations in thisa final rule.

Carrier agreed with the proposed violations, but requested that DOE further elaborate on the term "manufacturer" as it pertains to violations to include clarification that some manufacturers may also act as distributors, but are still subject to the fines of a prohibited act as a manufacturer. (Carrier, No. 97 at p. 4)

DOE agrees with Carrier's clarification that manufacturer-owned distributors are considered manufacturers. Because EPCA defines the term "distributor" as a person, *other than* a manufacturer or retailer, to whom a consumer product is delivered or sold for purposes of distribution in commerce, then a company that both manufactures and distributes is considered a manufacturer. 42 U.S.C. 6291(14). Therefore, manufacturer-owned distributors cannot be found to be routine violators as adopted in this rule, but are instead prohibited from knowingly selling a product to a distributor, contractor, or dealer with knowledge that the entity routinely violates any regional standard applicable to the product. (42 U.S.C. 6302, 10 CFR 429.102(a)(10))

To determine if a violation occurred, the Department explained it will conduct an investigation into the alleged misconduct. In a typical investigation, DOE may discuss the installation in question with the end user or the homeowner and other relevant parties, including the alleged violator. DOE may also request records from the dealer, contractor, distributor, and/or manufacturer if the Department has reasonable belief a violation occurred.

The Working Group recommended and DOE proposed in the November 2015 NOPR that if no violation is found, the Department should issue a case closed letter to the party being investigated. The Working Group also recommended that, if DOE finds that a contractor or dealer completed a noncompliant installation in one residence or an equivalent setting (*e.g.,* one store), but the violator remediated that violation by installing a compliant unit before DOE concluded its investigation, then DOE should issue a case closed letter to the party being investigated, as long as that person has no history of prior violations. The purpose of this practice would be to incentivize parties who, on one occasion, mistakenly install one noncompliant unit to replace the product and thereby not suffer any public stigma. However, if the noncompliant installation is not remediated and a violation is found, DOE should issue a public "Notice of Violation." The party found to be in violation can remediate the single violation and it will not count towards the finding of "routine violator" unless the party is found, in the course of a subsequent investigation, to have committed another violation. For more on remediation of a single violation, see section II.J. See 80 FR 72373, 72378 (Nov. 19, 2015).

In determining whether a party "routinely violates" a regional standard, the Working Group recommended that DOE consider the following factors:

- Number of violations (in both current and past investigations);
- Length of time over which the violations were committed;
- Ratio of compliant to noncompliant installations or sales;
- Percentage of employees committing violations;
- Evidence of effort or intent to commit violations;
- Evidence of training or education provided on regional standards; and
- Subsequent remedial actions.

The Working Group also agreed that DOE should consider whether the routine violation was limited to a specific contractor or distribution location. DOE would rely on the same factors considered in determining whether a routine violation occurred.

Interested parties submitted comments supporting the factors DOE proposed to consider to determine if a violation is routine. (ADP, No. 93 at p. 2; Rheem, No. 98 at p. 3; Carrier, No. 97 at p. 4; Lennox, No. 95 at p. 3) Accordingly, DOE is adopting these factors are part of its provisions for identifying routine violations.

In the November 2015 NOPR, DOE proposed adopting the Working Group's recommendation that DOE issue a "Notice of Finding of Routine Violator" if the Department determines that a violator routinely violated a regional standard. This notice would identify the party found to be a routine violator and explain the scope of the violation. Additionally, if DOE, in its discretion, finds that the routine violation was limited to a specific location, DOE may in the Notice of Finding of Routine Violation state that the prohibition on manufacturer sales is limited to a particular contractor or distribution location This notice would be both posted to the Department's enforcement Web site[15] and would be emailed to those signed up for email updates.[16] See 80 FR 72373, 72378 (Nov. 19, 2015).

DOE also proposed that if DOE makes a finding of routine violation, the violator has the right to file an administrative appeal of the finding. Any appeal of a Notice of Finding of Routine Violation would be required to be filed within 30 days of the issuance of the notice. The appeal would be reviewed by DOE's Office of Hearings and Appeals. The appeal must present information rebutting the finding of routine violation. The appeal will be decided within 45 days of filing of the appeal. The violator may file a Notice of Intent to Appeal with the DOE Office of Hearings and Appeals. If this notice of intent is filed within three business days of the Notice of Finding of Routine Violation, then manufacturers may continue to sell products to the routine violator during the pendency of the appeal. See section II.J for more details on sales during the pendency of an appeal. See 80 FR 72373, 72378 (Nov. 19, 2015).

In response, the CA IOUs commented that DOE should be aware of the potential for units to cross region borders illegally, as once a condenser unit is shipped to a given region, there would be potential for it to cross region borders. The CA IOUs stated that the ability to label the distributor as a "routine violator" would help this problem. Further, the CA IOUs supported publically disciplining distributors who sell non-compliant units by labeling such distributors as "routine violators." (CA IOUs, No. 99 at p. 2)

DOE received no other comments related to its proposed regulatory framework for violations and routing violations. Therefore, in this rule DOE adopts its proposals related to issuing a Notice of Violation or Notice of Finding of Routine Violations. Further, DOE adopts its proposal to allow findings of routine violation to be appealed. The CA IOUs recommendation goes beyond the scope of DOE's proposal and is not addressed in this rulemaking.

---

[15] DOE's enforcement Web site is: *http://energy.gov/gc/enforcement.*

[16] Sign up for updates at *https://public.govdelivery.com/accounts/USEERE/subscriber/new* and select "Regional Enforcement Standards" under "Appliance and Equipment Standards."

J. Remediation

DOE proposed in its November 2015 NOPR a concept for remediation that would apply to any party found to be in violation of the regional standards. The Department explained that any violator may remediate by replacing the noncompliant unit at cost to the violator; the end user could not be charged for any costs of remediation. The violator would be required to provide to DOE the serial number of any outdoor unit and/or indoor unit installed not in compliance with the applicable regional standard and the serial number(s) of the replacement unit(s) to be checked by the Department against warranty and other replacement claims. If the remediation is approved by the Department, then DOE would issue a Notice of Remediation and the violation would not count toward a finding of "routine violator." 80 FR 72373, 72379 (Nov. 19, 2015).

Commenters agreed with the proposed concept for remediation. (ADP, No. 93 at p. 2; Carrier, No. 97 at p. 5; HARDI, No. 94 at p. 2; Lennox, No. 95 at p. 3; Rheem, No. 98 at p. 3). Accordingly, DOE adopts the proposed concept for remediation in this final rule.

K. Manufacturer Liability

In accordance with the Department's regulations on prohibited acts, manufacturers may be fined for "knowingly sell[ing] a product to a distributor, contractor, or dealer with knowledge that the entity routinely violates any regional standard applicable to the product." (42 U.S.C. 6302, 10 CFR 429.102(a)(10)) The Working Group had significant discussions on the scope of the term "product" as it relates to this prohibited act. During the Working Group meetings, the Department explained that it interprets the term "product" to include all classes of central air conditioners and heat pumps found within 10 CFR 430.32(c). Ultimately, the Working Group could not come to consensus on whether the scope of any prohibition on sales could be limited to split-system air conditioners and single-package air conditioners instead of the Department's interpretation.[17] 80 FR 72373, 72380 (Nov. 19, 2015).

EPCA defines a "central air conditioner" as a "product . . . which . . . is a heat pump or a cooling only unit" and refers to all central air conditioners as one "product." (42 U.S.C. 6291(21)) Therefore, to be consistent with EPCA, DOE proposed in the November 2015 NOPR to interpret the term "product" to be inclusive of all central air conditioner and heat pump product classes listed in 10 CFR 430.32(c), meaning that manufacturers may be subject to civil penalties for sales to a routine violator of any unit within the central air conditioning product classes. 80 FR 72373, 72380 (Nov. 19, 2015).

DOE also proposed that, if a manufacturer sells a central air conditioner (including heat pumps) to a routine violator after a Notice of Finding of Routine Violation has been issued, then the manufacturer would be liable for civil penalties. 80 FR 72373, 72380 (Nov. 19, 2015). The maximum fine a manufacturer is subject to is $200 per unit sold to a routine violator. (42 U.S.C. 6303(d), 10 CFR 429.120)

CA IOUs commented in support of DOE's decision to fine manufacturers for violations of the regional standard. CA IOUs explained that ultimately manufacturers are responsible for where their units are shipped for end use sale and should bear the penalty of being out of compliance. (CA IOUs, No. 99 at p. 2)

In response, DOE clarifies that manufacturers are only subject to penalties if they commit a prohibited act. See 10 CFR 429.120. The violations DOE established in this rulemaking are a pathway to establishing whether or not a manufacturer is knowingly selling to a distributor, contractor, or dealer with knowledge that the entity routinely violates any regional standard.

DOE also proposed to adopt the Working Group's recommendation that DOE provide manufacturers with 3 business days from the issuance of a Notice of Finding of Routine Violation to stop all sales of central air conditioners and heat pumps to the routine violator. During this time, manufacturers would not be liable for sales to a routine violator. DOE noted that, consistent with its penalty guidance,[18] it would consider the manufacturer's efforts to stop any sales in determining whether (or to what extent) to assess any civil penalties for sales to a routine violator after that three day window. 80 FR 72373, 72380 (Nov. 19, 2015).

If the routine violator is appealing the finding, the Working Group recommended that manufacturers be allowed to continue to sell central air conditioners and heat pumps to the routine violator during the pendency of the appeal. In order to provide parties notice that a routine violator is appealing the determination, the routine violator must file a Notice of Intent to Appeal with the Office of Hearings and Appeals within three business days after the issuance of the Notice of Finding of Routine Violator. If the finding is ultimately upheld, then the manufacturers could face civil penalties for sale of any products rated below the regional standards to the routine violator. DOE proposed to adopt this recommendation in the November 2015 NOPR. 80 FR 72373, 72380 (Nov. 19, 2015).

The Working Group also recommended that DOE provide an incentive for manufacturers to report routine violators. The Working Group recommended that if a manufacturer has knowledge of a routine violator, then the manufacturer can be held liable for all sales made after the date such knowledge is obtained by the manufacturer. However, if the manufacturer reports such knowledge to DOE within 15 days of receipt of the knowledge, then the Department will not hold the manufacturer liable for sales to the suspected routine violator made prior to notifying DOE. DOE proposed to adopt this recommendation in the November 2015 NOPR. 80 FR 72373, 72380 (Nov. 19, 2015).

In the November 2015 NOPR, DOE proposed to adopt the clarifications of manufacturer liability, as recommended by the Working Group, and requested comment on this proposal. Interested parties submitted comments on DOE's proposed scheme for manufacturer liability. One commenter supported DOE's proposed scheme. Some commenters agreed in part with DOE's proposed scheme but offered additional, suggested clarification. Some commenters disagreed with DOE's use of the term "product."

Lennox supported DOE's proposed scheme for manufacturer liability. (Lennox, No. 95 at p. 3) ADP agreed with DOE's proposal as it pertains to independent coil manufacturers, with the clarification that the independent coil manufacturer would not be responsible for noncompliant installations performed after the combination has been removed from the certification database and is no longer being distributed in commerce. (ADP, No. 93 at p. 2) Rheem agreed with the proposed scheme. (Rheem, No. 98 at p. 3) Carrier also expressed in basic agreement with the scheme for manufacturer liability. (Carrier, No. 97 at p. 5)

---

[17] For more details regarding this discussion, see the public meeting transcript for October 24, 2014, No. 88.

[18] The DOE civil penalty guidance is available at *http://energy.gov/gc/enforcement* under "Enforcement Guidance."

Accordingly, DOE adopts the proposed framework and procedures for making findings of violations.

Rheem commented that the prohibited act should only apply to manufacturers of products subject to regional standards. Rheem stated that the November 2015 NOPR language gives the Department the ability to fine manufacturers for the sale of product even if there is no regional standard applicable to that product and stated that it believes this to be outside the authority of this NOPR. (Rheem, No. 98 at p. 3) Rheem further stated that regional standards products were specifically defined in the ground rules of the working group as residential split-system and single package air conditioners that are subject to the regional standards. (Rheem, No. 98 at p. 3). Carrier also did not agree with the NOPR's scope relative to manufacturer's liability for covered products. Carrier stated the focus of the Working Group was on split systems and single package systems. Carrier also stated that manufacturer liability should be limited to these specific classes that are not subject to regional standards,[19] and fully supported AHRI's position in their more extensive comments relative to this matter. (Carrier, No. 97 at p. 5) AHRI stated that to accept DOE's expansive view of the "products" affected by the regional standards enforcement would result in DOE's ability to ban the sale of products that are not subject to a regional standard, and that are fully compliant with the applicable national standard. AHRI believed that DOE ignored the Working Group's Ground Rules, which referred specifically to split systems and single package systems. AHRI commented that, instead, when interpreting the prohibited act as it relates to regional standards, DOE focused exclusively on the word "product" in isolation from both the Working Group's approved scope and EPCA's statutory text. (AHRI, No. 101 at p. 5) AHRI stated that manufacturers of central air conditioning products (other than split system and single package) were provided no notice that the Working Group would be developing an enforcement standard that would ban the sale of their equipment even though it is not subject to regional standards. (AHRI, No. 101 at pp. 5–6)

As DOE explained in the November 2015 NOPR, EPCA defines a "central air conditioner" as a "product . . . which . . . is a heat pump or a cooling only unit" and refers to all central air conditioners as one "product." (42 U.S.C. 6291(21)) EPCA also sets forth a prohibited act for a manufacturer to "knowingly sell a product to a distributor, contractor, or dealer with knowledge that the entity routinely violates *any* regional standard applicable to the product." (42 U.S.C. 6302(a)(6) emphasis added) Accordingly, DOE interprets the term "product" in 42 U.S.C. 6302 to be inclusive of all central air conditioner and heat pump product classes listed in 10 CFR 430.32(c), meaning that manufacturers may be subject to civil penalties for sales to a routine violator of any unit within the central air conditioning product classes. 80 FR 72373 (November 19, 2015).

In response to Rheem, DOE notes that, with respect to national standards, the prohibited act reads "for any manufacturer or private labeler to distribute in commerce any new covered product which is not in conformity with an applicable energy conservation standard established in or prescribed under this part, except to the extent that the new covered product is covered by a regional standard that is more stringent than the base national standard." (42 U.S.C. 6302(a)(5)) In contrast, the prohibited act with respect to regional standards does not mention the "conformity" of the product being distributed with respect to the regional standard. Instead, the relevant analysis is whether the sale of the product is to a routine violator. (*See* 42 U.S.C. 6302(a)(6).)

In arriving at its interpretation, DOE notes that the installer, distributor, and manufacturer have multiple opportunities to remediate violations and to avoid further violations. In the course of the negotiation, the regulated parties have ensured that there is a very high bar for DOE to make a finding that a manufacturer has knowingly sold a product to a distributor, contractor, or dealer with knowledge that the entity is a routine violator. Therefore, not only does the plain language of EPCA support the interpretation, DOE finds that the remedy is proportionate to the violation.

AHRI, Carrier and Rheem suggested in their comments that DOE's interpretation is at odds with the scope of the Working Group. DOE disagrees. The parties agreed to negotiate a procedure for enforcement of regional standards under 42 U.S.C. 6295(o)(6)(G), which are applicable only to split systems and single package CAC systems. DOE is not enforcing a regional standard against heat pumps. DOE's interpretation is that the ramifications for a distributor, contractor, or dealer that is a routine violator of regional standards include a limitation on the availability of all classes of central air conditioners. Nothing prevents manufacturers from selling to other distributors, contractors, or dealers.

With respect to AHRI's contention that this interpretation results in DOE's ability to ban the sale of products that are not subject to a regional standard, DOE notes that it is not banning the sale of products—it is only asserting authority to assess civil penalties for commission of prohibited acts. As mentioned above, manufacturers can continue to sell products to entities that have not been found to routinely violate the regional standards without penalty. Manufacturers can continue to sell central air conditioners to entities that have been found to routinely violate the regional standards, albeit subject to penalty. Manufacturers may continue to sell other types of covered products or equipment (other than central air conditioners) and products that are not subject to standards to entities that have been found to routinely violate the regional standards without penalty. Manufacturers are only subject to penalty for the sale of central air conditioners to a distributor, contractor, or dealer that has been found to routinely violate the regional standards.

AHRI also commented that this interpretation would prevent manufacturers from selling products that are fully compliant with the applicable national standard to an entity that has been found to routinely violate the regional standards. Again, manufacturers could do so but would be subject to penalty—it is not a ban. More to the point, however, DOE agrees that it would be a prohibited act to sell a central air conditioner that meets the base national standard to an entity that has been found to routinely violate the regional standards. This is entirely consonant with the statutory language, which is markedly different with respect to regional standards than national standards. If an entity has failed to remediate past violations and has continued to violate the regional standards, there should be a significant consequence. The likely lack of availability of central air conditioners should produce a significant incentive for a routine violator to remediate past violations—or, hopefully, to avoid being identified as a routine violator at all.

As DOE noted in the NOPR, nothing in this rulemaking impacts DOE's ability to determine that a manufacturer has manufactured and distributed a noncompliant central air conditioner in accordance with the existing procedures at 10 CFR 429.104–114. Furthermore, those processes apply to DOE's determination of a manufacturer's manufacture and distribution of a central air conditioner that fails to meet a regional standard. With respect to liability, if DOE determines that a model of condensing unit fails to meet the applicable regional standard(s) when tested in a combination certified by the same manufacturer (*i.e.*, one entity manufactures both the indoor coil and the condensing unit), the condensing unit manufacturer will be responsible for this model's noncompliance. If DOE determines that a basic model fails to meet regional standards when tested in a combination certified by a manufacturer other than the outdoor unit manufacturer (*e.g.*, an independent coil manufacturer (ICM)), the certifying manufacturer will be responsible for this combination's noncompliance. The responsible manufacturer will be liable for distribution in commerce of noncompliant units. That manufacturer can minimize liability by demonstrating on a unit-by-unit basis that the noncompliant combination was installed in a region where it would meet the standards. For example, if a 14 SEER split-system air conditioner was tested by the Department and determined to be 13.5 SEER, then the manufacturer may minimize its liability by proving only a portion of sales for this combination was installed in the Southeast and Southwest. Manufacturers represented during the course of the negotiations that the bulk of sales are of minimally compliant units and so they expect most of the products that comply with the Southeast and Southwest regional standards would be sold in those regions. Given this, the Working Group agreed that there should be a presumption that the units were sold in a region subject to a regional standard and that DOE would presume all units of a model rated as compliant with a regional standard but determined to be noncompliant with that standard were in fact installed illegally. Manufacturers can rebut this presumption by providing evidence that a portion of the units were instead installed in a location where they would have met the applicable energy conservation standards. 80 FR 72373, 72380 (Nov. 19, 2015).

---

[19] Read in context, DOE believes Carrier intended to say that liability should be limited to classes that are subject to regional standards.

L. Impact of Regional Enforcement on National Impacts Analysis

In the June 2011 DFR, DOE considered the economic impacts of amending the standards for central air conditioners and heat pumps. Included in the economic analyses was a National Impacts Analysis (NIA) which estimated the energy savings and the net present value (NPV) of those energy savings that consumers would receive from the new energy efficiency standards of central air conditioners (CAC) and heat pumps (HP). This NPV was the estimated total value of future operating-cost savings during the analysis period (2015–2045), minus the estimated increased product costs (including installation), discounted to 2011. However, DOE did not account for the financial burden on distributors and installers related to record retention requirements necessary to demonstrate compliance with the regional standards in the June 2011 DFR.

From the enforcement plan proposed in the November 2015 NOPR, DOE estimated that manufacturers, distributors, and contractors face some financial burden related to the proposed record retention requirements. DOE assumed that the proposed records retention requirements would cause manufacturers, distributors, and contractors additional labor costs from collecting and filing such records. These labor costs would be an annual burden to the market participants. At the Working Group public meetings, distributors stated that, if they had to update their enterprise resource planning (ERP) systems to track the necessary information electronically, initial costs could be as high as $46,340,000. DOE did not receive any quantitative comments on its assumptions for the financial burden from the proposed record retention requirements, but upon review, has increased the estimated total annual cost to manufacturers. Because DOE is not requiring distributors to track the necessary information electronically and therefore distributors are not required to update their ERP systems, DOE has not included that cost in the updated cost of retaining records on each market participant, which is summarized in Table II.2.

TABLE II.2—COST OF RECORDS RETENTION DUE TO REGIONAL STANDARDS ENFORCEMENT FOR CENTRAL AIR CONDITIONER AND HEAT PUMP MARKET PARTICIPANTS

	Manufacturers	Distributors	Contractors
Total Annual Burden Hours	574,167	287,083	359,949
Estimated Total Annual Cost	$57,416,667	$2,081,354	$2,609,631

In the November 2015 NOPR, DOE re-evaluated the NIA to include the cost of the proposed record retention requirements to manufacturer, distributors, and contractors. DOE conservatively estimated the consumer benefits by assuming that the annual cost from the proposed record retention requirements would be passed on to consumers and thus decreasing the NPV. DOE revised this analysis for the final rule using the updated costs to manufacturers and excluding initial ERP costs, which are not required by the rule. The updated NPV results are summarized in Table II.3. The impact of including the proposed record retention requirement costs on the NPV is estimated to reduce the benefit by $1.86 billion (11-percent) at a 3% discount rate and $0.99 billion (25-percent) at a 7% discount rate. The costs of the record retention requirements are estimated to have no impact on national energy savings. DOE's economic justification of the energy conservation standards chosen and published in the 2011 DFR would be unaffected by the quantification and inclusion of enforcement plan costs. In this final rule, DOE reaffirms the 2011 DFR energy conservation standards based on this analysis and adopts its evaluation in the November 2015 NOPR. 80 FR 72373, 72382 (Nov. 19, 2015).

TABLE II.3—NATIONAL IMPACTS ANALYSIS RESULTS WITH COSTS FROM PROPOSED REGIONAL ENFORCEMENT PLAN FOR CENTRAL AIR CONDITIONERS AND HEAT PUMPS

	National impacts estimated from 2011 DFR for the chosen energy conservation standards	National impacts estimated from 2011 DFR for the chosen energy conservation standards with enforcement plan costs
Savings (quads)	3.20 to 4.22	3.20 to 4.22.
NPV of Consumer Benefits at 3% discount rate (2009$ billion)	14.73 to 17.55	12.88 to 15.69.
NPV of Consumer Benefits at 7% discount rate (2009$ billion)	3.93 to 4.21	2.94 to 3.22.

III. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget (OMB) has determined that test procedure rulemakings do not constitute "significant regulatory actions" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a regulatory flexibility analysis (FRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003 to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://energy.gov/gc/.*

DOE reviewed the proposed requirements under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. As discussed in more detail in this preamble, DOE found that the entities impacted by this rule (central air conditioning manufacturers, distributors, and contractors) could potentially experience a financial burden associated with these new requirements. Additionally, the majority of central air conditioning contractors and distributors are small business as defined by the Small Business Administration (SBA). DOE determined that it could not certify that the proposed rule, if promulgated, would not have a significant effect on a substantial number of small entities. Therefore, DOE has prepared an RFA for this rulemaking. The RFA describes potential impacts on small businesses associated with the requirements adopted in this rulemaking.

DOE has transmitted a copy of this RFA to the Chief Counsel for Advocacy of the Small Business Administration for review.

1. Description and Estimated Number of Small Entities Regulated

The SBA has set a size threshold for manufacturers, distributors, and contractors of central air conditioning products that define those entities classified as "small businesses." DOE used SBA's size standards to determine whether any small businesses would be impacted by this rule. 65 FR 30836, 30849 (May 15, 2000), as amended at 65 FR 53533, 53545 (Sept. 5, 2000) and codified at 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description, and are available at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.* The size standards and NAICS codes relevant to this rulemaking are listed in Table III–1.

To estimate the number of companies that could be small business manufacturers, distributors, and contractors of equipment covered by this rulemaking, DOE conducted a market survey using available public information. DOE's research involved examining industry trade association Web sites, public databases, and individual company Web sites. DOE also solicited information from industry representatives such as AHRI, HARDI, ACCA, and PHCC. DOE screened out companies that do not offer products covered by this rulemaking or are not impacted by this rulemaking, do not meet the definition of a "small business," or are foreign owned and operated. In addition, DOE prepared an IRFA and requested comment in the November 2015 NOPR proposing the concepts adopted in this final rule. DOE did not receive any substantive comments in response to its IRFA.

TABLE III.1—SMALL BUSINESS CLASSIFICATION SUMMARY TABLE

Impacted entity	NAICS Code	NAICS Definition of small business	Total number of impacted businesses	Total number of small businesses
Contractors [20]	238220	$15 million or less in revenue	[21] 22,207	21,763
Distributors	423730	100 or less employees	[22] 2,317	2,000
Manufacturers	333415	750 or less employees	29	12

---

[20] The number of impacted contractors and small contractors is based on the number of contractors installing in the Southwest and Southeast regions.

[21] Chapter 18: Regional Standards Impacts on Market Participants. Technical Support Document: Energy Efficiency Program for Consumer Products: Residential Central Air Conditioners, Heat Pumps, and Furnaces. *http://www.regulations.gov/#!documentDetail;D=EERE-2011-BT-STD-0011-0012.*

[22] "Statistics of U.S. Businesses: 2008: NAICS 423730—HVAC equip. merchant wholesalers United States." U.S. Census Bureau. *http://www.census.gov/epcd/susb/2008/us/us423730.htm.*

2. Description and Estimate of Regional CAC Requirements

As discussed in the preamble of this rule, the Working Group recommended an enforcement plan for central air conditioners that would include public awareness efforts, records retention requirements, and voluntary efforts like remediation and labeling. The Working Group also made explicit the terms "violation" and "routine violator." While most of the regulations in this rule will not have an impact on manufacturers, distributors, and contractors that adhere to the central air conditioner regional standards, the records retention requirements may result in some financial burden.

At the Working Group meetings. HARDI stated that distributors track equipment and sales in ERP systems and are expected to incorporate the proposed recordkeeping requirements into their ERP systems. HARDI expected that 40% of distributors currently retain the proposed records and will not need to update their ERP systems. HARDI expected 50% of distributors would need to make some changes to their ERP systems and 10% of distributors would need to make major changes to their ERP system. HARDI expected that small distributors are more likely to require major changes to their ERP systems because typically small distributors have older and more inflexible systems. HARDI estimated that changes to ERP systems to accommodate the record retention proposals may cost $20,000 to $100,000 depending on the type of change needed to the system. According to HARDI, the entire central air conditioner distribution industry would incur an initial conversion cost of around $46,340,000 to modify the ERP systems. To help alleviate some of the financial burden, the Working Group recommended that DOE not require distributors to retain records for sales of central air conditioner indoor coils or air handlers, which were identified as difficult components to track for the distributors. Additionally, the Working Group recommended that distributors should not have to start retaining records until November 30, 2015, at the earliest, which DOE has delayed until August 15, 2016.

The Working Group worked to negotiate records retention requirements that would have limited financial burden on the impacted parties—manufacturers, distributors, and contractors. The Working Group made a few general provisions regarding the records retention requirements to help mitigate some of the financial burden. The Working Group tried to reduce the impact of the records retention requirements by staggering the length of time for which records must be maintained. Manufacturers, the entities understood to have the most resources and sophistication, would have to retain records for the longest time period (60 months); distributors would have to retain records for less time (54 months); and contractors would have to retain records for the least amount of time (48 months). Additionally, in the case that records are requested, the Working Group recommended that the party from whom the records were requested should have an extended period of 30 days to produce such records. The Working Group also explicitly recommended that manufacturers, distributors, and contractors should not have to create new forms to retain such records, and that the records would not have to be retained electronically.

DOE expects central air conditioning manufacturers to be the least burdened entity of all the affected entities by the record retention requirements in this final rule. Manufacturers have the fewest record retention requirements. Many of the record retention requirements being in this final rule expand on DOE's existing certification requirements and thus should only slightly increase the recordkeeping burden. DOE does not expect manufacturers to incur any capital expenditures as a result of the proposals since the rulemaking does not impose any product-specific requirements that would require changes to existing plants, facilities, product specifications, or test procedures. Rather, this proposed rule imposes record retention requirements, which may have a slight impact on labor costs. DOE included certification and enforcement requirements associated with the regional standards for central air conditioners in the June 27, 2011 [23] energy conservation standards final rule for central air conditioners and heat pumps. To avoid the potential costs to distributors, the Working Group recommended DOE not require electronic record retention, and DOE is neither requiring records to be retained in electronic form nor mandating that distributors make changes in their ERP systems to retain the information proposed in this rule.

DOE believes central air conditioning contractors will experience a minimal recordkeeping burden. DOE is limiting the records retention requirements on contractors to installations in the Southeast and Southwest. For all central air conditioner installations in those regions, contractors must keep a record of installation location, date of installation, and purchaser. Contractors must keep records specific to the type of units (outdoor condensing unit, indoor coil or air handler, or single-package air conditioner) installed as well. A contractor trade association remarked at the public meetings that most contractors already retain such records and the record retention requirements would have limited financial impacts. (ACCA, Public Meeting Transcript, No. 77 at 12–13) DOE estimates that any additional expense caused by the records requirements adopted in this rule would be related to the time required to file these records. DOE estimates that contractors may spend an additional 10 minutes per installation to comply with the records retention requirements.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being considered.

4. Significant Alternatives to the Rule

DOE could mitigate the potential impacts on small manufacturers, distributors, or contractors by reducing or eliminating the proposed types of information to be maintained. However, these requirements were negotiated as an acceptable compromise among the participants in the Working Group. While there may be some financial burden, the Working Group unanimously agreed to the record retention requirements for manufacturers, distributors, and contractors. Furthermore, DOE believes that the record retention requirements are the least burdensome requirements possible to provide DOE sufficient information to determine whether manufacturers, distributors and contractors are complying with regulatory requirements. Thus, in the November 2015 NOPR, DOE rejected the alternative of reducing or eliminating the record retention requirements and is proposing these record retention requirements for the aforementioned parties. DOE adopts this proposal in this final rule. 80 FR 72373, 72383–72384 (Nov. 19, 2015).

C. Review Under the Paperwork Reduction Act of 1995

1. *Description of the Requirements:* In this final rule, DOE is adopting record

---

[23] Chapter 12: Manufacturer Impact Analysis. Technical Support Document: Energy Efficiency Program for Consumer Products: Residential Central Air Conditioners, Heat Pumps, and Furnaces. *http://www.regulations.gov/#!documentDetail;D=EERE-2011-BT-STD-0011-0012.*

retention requirements for central air conditioner manufacturers, distributors, and contractors. DOE requested approval for a new information collection associated with these requirements. These requirements were developed as part of a negotiated rulemaking effort for regional central air conditioner enforcement. These requirements are described in detail in section II.H.

2. *Information Collection Request Title:* Enforcement of Regional Standards.

3. *Type of Request:* New.

4. *Purpose:* Generally, DOE is requiring that manufacturers retain records of the model number and serial number for all split system and single-package air conditioners, when these units were manufactured, when these units were sold, and to whom the units were sold. Manufacturers must retain these records for 60 months. Distributors must retain the manufacturer, model number and serial number for all their split system outdoor condensing units and single-package units. In addition, distributors must keep track of when and from whom each of these types of units was purchased, and when and to whom each of these units was sold. Distributors must retain these records for 54 months. Contractors must retain records of all split system and single-package air conditioner installations in the Southeast and Southwest region. These records are required to include what was installed (*e.g.*, manufacturer and model number), date of sale, and the party to whom the unit was sold. Contractors must retain these records for 48 months.

This final rule primarily requires central air conditioner manufacturers, distributors, and contractors to retain records for CAC installations. If DOE has a "reasonable belief" that an installation in violation of regional standards occurred, then it may request records specific to an ongoing investigation from the relevant manufacturer(s), distributor(s), and/or contractor(s). The Working Group recommended that DOE determine if it has a "reasonable belief" of a CAC violation based on the factors described in section II.I. Once DOE establishes reasonable belief and requests records from the relevant parties, then the entity from whom DOE requested records has 30 days to produce those records. The party from whom DOE requested records may ask for additional time with a written explanation of the circumstances.

The following are DOE estimates of the total annual recordkeeping burden imposed on manufacturers, distributors, and contractors of central air conditioners. These estimates take into account the time necessary collect, organized and store the record required by this rulemaking. See the supporting statement for detailed explanations of the estimates.

Manufacturers

Estimated Number of Impacted Manufacturers: 29.

Estimated Time per Record: 10 minutes.

Estimated Total Annual Burden Hours: 574,167 hours.

Estimated Total Annual Cost to the Manufacturers: $57,416,667.

Distributors

Estimated Number of Impacted Distributors: 2,317.

Estimated Time per Record: 5 minutes.

Estimated Total Annual Burden Hours: 287,083 hours.

Estimated Total Annual Cost to the Distributors: $2,081,354.

Contractors

Estimated Number of Impacted Contractors: 22,207.

Estimated Time per Record: 10 minutes per installation.

Estimated Total Annual Burden Hours: 359,949 hours.

Estimated Total Annual Cost to the Contractors: $2,609,631.

5. *Annual Estimated Number of Respondents:* 24,553.

6. *Annual Estimated Number of Total Responses:* 24,553.

7. *Annual Estimated Number of Burden Hours:* 1,221,199.

8. *Annual Estimated Reporting and Recordkeeping Cost Burden:* $62,107,652.

D. Review Under the National Environmental Policy Act of 1969

DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this rule would adopt changes to the manner in which regional standards for central air conditioners are enforced, which would not affect the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this final rule will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This final rule adopting a regional standards enforcement plan for central air conditioners is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition. This final rule does not require use of any commercial standards.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this final rule before its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Incorporation by reference, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on June 10, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE amends parts 429 and 430 of chapter II of title 10, Code of Federal Regulations, as set forth below:

PART 429—CERTIFICATION, COMPLIANCE AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Amend § 429.102 to add paragraph (c) to read as follows:

§ 429.102 Prohibited acts subjecting persons to enforcement action.

* * * * *

(c) *Violations of regional standards.* (1) It is a violation for a distributor to knowingly sell a product to a contractor or dealer with knowledge that the entity will sell and/or install the product in violation of any regional standard applicable to the product.

(2) It is a violation for a distributor to knowingly sell a product to a contractor or dealer with knowledge that the entity routinely violates any regional standard applicable to the product.

(3) It is a violation for a contractor or dealer to knowingly sell to and/or install for an end user a central air conditioner subject to regional standards with the knowledge that such product will be installed in violation of any regional standard applicable to the product.

(4) A "product installed in violation" includes:

(i) A complete central air conditioning system that is not certified as a complete system that meets the applicable standard. Combinations that were previously validly certified may be installed after the manufacturer has discontinued the combination, provided the combination meets the currently applicable standard.

(ii) An outdoor unit with no match (*i.e.*, that is not offered for sale with an indoor unit) that is not certified as part of a combination that meets the applicable standard.

(iii) An outdoor unit that is part of a certified combination rated less than the standard applicable in the region in which it is installed.

■ 3. Add an undesignated center heading after § 429.134 in subpart C to read as follows:

Regional Standards Enforcement Procedures

■ 4. Add § 429.140 to subpart C to read as follows:

§ 429.140 Regional standards enforcement procedures.

Sections 429.140 through 429.158 provide enforcement procedures specific to the violations enumerated in § 429.102(c). These provisions explain the responsibilities of manufacturers, private labelers, distributors, contractors and dealers with respect to central air conditioners subject to regional standards; however, these provisions do not limit the responsibilities of parties otherwise subject to 10 CFR parts 429 and 430.

■ 5. Add § 429.142 to subpart C to read as follows:

§ 429.142 Records retention.

(a) *Record retention.* The following entities must maintain the specified records—(1) *Contractors and dealers.* (i) Contractors and dealers must retain the following records for at least 48 months from the date of installation of a central air conditioner in the states of Alabama, Arizona, Arkansas, California, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, Nevada, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, or Virginia or in the District of Columbia:

(A) *For split-system central air conditioner outdoor units:* The manufacturer name, model number, serial number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number); and

(B) *For split-system central air conditioner indoor units:* The manufacturer name, model number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number).

(ii) Contractors and dealers must retain the following, additional records for at least 48 months from the date of installation of a central air conditioner in the states of Arizona, California, Nevada, and New Mexico:

(A) *For single-package central air conditioners:* The manufacturer name, model number, serial number, location of installation (including street address, city, state, and zip code), date of installation, and party from whom the unit was purchased (including person's name, full address, and phone number).

(B) [Reserved]

(2) *Distributors.* Beginning July 1, 2016, all distributors must retain the following records for no less than 54 months from the date of sale:

(i) *For split-system central air conditioner outdoor units:* The outdoor unit manufacturer, outdoor unit model number, outdoor unit serial number, date unit was purchased from manufacturer, party from whom the unit was purchased (including company or individual's name, full address, and phone number), date unit was sold to contractor or dealer, party to whom the unit was sold (including company or individual's name, full address, and phone number), and, if delivered, delivery address.

(ii) *For single-package air conditioners:* The manufacturer, model number, serial number, date unit was purchased from manufacturer, party from whom the unit was purchased (including company or individual's name, full address, and phone number), date unit was sold to a contractor or dealer, party to whom the unit was sold (including company or individual's name, full address, and phone number), and, if delivered, delivery address.

(3) *Manufacturers and private labelers.* All manufacturers and private labelers must retain the following records for no less than 60 months from the date of sale:

(i) *For split system air conditioner outdoor units:* The model number, serial number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number);

(ii) *For split system central air conditioner indoor units:* The model number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number); and

(iii) *For single-package central air conditioners:* The model number, serial number, date of manufacture, date of sale, and party to whom the unit was sold (including person's name, full address, and phone number).

(b) [Reserved]

■ 6. Add § 429.144 to subpart C to read as follows:

§ 429.144 Records request.

(a) DOE must have reasonable belief a violation has occurred to request records specific to an on-going investigation of a violation of central air conditioner regional standards.

(b) Upon request, the manufacturer, private labeler, distributor, dealer, or contractor must provide to DOE the relevant records within 30 calendar days of the request.

(1) DOE, at its discretion, may grant additional time for records production if the party from whom records have been requested has made a good faith effort to produce records.

(2) To request additional time, the party from whom records have been requested must produce all records gathered in 30 days and provide to DOE a written explanation of the need for additional time with the requested date for completing the production of records.

■ 7. Add § 429.146 to subpart C to read as follows:

§ 429.146 Notice of violation.

(a) If DOE determines a party has committed a violation of regional standards, DOE will issue a Notice of Violation advising that party of DOE's determination.

(b) If, however, DOE determines a noncompliant installation occurred in only one instance, the noncompliant installation is remediated prior to DOE issuing a Notice of Violation, and the party has no history of prior violations, DOE will not issue such notice.

(c) If DOE does not find a violation of regional standards, DOE will notify the party under investigation.

■ 8. Add § 429.148 to subpart C to read as follows:

§ 429.148 Routine violator.

(a) DOE will consider, *inter alia,* the following factors in determining if a person is a routine violator: Number of violations in current and past cases, length of time over which violations occurred, ratio of compliant to noncompliant installations or sales, percentage of employees committing violations, evidence of intent, evidence of training or education provided, and subsequent remedial actions.

(b) In the event that DOE determines a person to be a routine violator, DOE will issue a Notice of Finding of Routine Violation.

(c) In making a finding of Routine Violation, DOE will consider whether the Routine Violation was limited to a specific location. If DOE finds that the routine violation was so limited, DOE may, in its discretion, in the Notice of Finding of Routine Violation limit the prohibition on manufacturer and/or private labeler sales to a particular contractor or distribution location.

■ 9. Add § 429.150 to subpart C to read as follows:

§ 429.150 Appealing a finding of routine violation.

(a) Any person found to be a routine violator may, within 30 calendar days after the date of Notice of Finding of Routine Violation, request an administrative appeal to the Office of Hearings and Appeals.

(b) The appeal must present information rebutting the finding of violation(s).

(c) The Office of Hearings and Appeals will issue a decision on the appeal within 45 days of receipt of the appeal.

(d) A routine violator must file a Notice of Intent to Appeal with the Office of Hearings and Appeals within three business days of the date of the Notice of Finding of Routine Violation, serving a copy on the Office of the Assistant General Counsel for Enforcement to retain the ability to buy central air conditioners during the pendency of the appeal.

■ 10. Add § 429.152 to subpart C to read as follows:

§ 429.152 Removal of finding of "routine violator".

(a) A routine violator may be removed from DOE's list of routine violators through completion of remediation in accordance with the requirements in § 429.154.

(b) A routine violator that wants to remediate must contact the Office of the Assistant General Counsel for Enforcement via the point of contact listed in the Notice of Finding of Routine Violation and identify the distributor(s), manufacturer(s), or private labeler(s) from whom it wishes to buy compliant replacement product.

(c) DOE will contact the distributor(s), manufacturer(s), or private labeler(s) and authorize sale of central air conditioner units to the routine violator for purposes of remediation within 3 business days of receipt of the request for remediation. DOE will provide the manufacturer(s), distributor(s), and/or private labeler(s) with an official letter authorizing the sale of units for purposes of remediation.

(d) DOE will contact routine violators that requested units for remediation within 30 days of sending the official letter to the manufacturer(s), distributor(s), and/or private labeler(s) to determine the status of the remediation.

(e) If remediation is successfully completed, DOE will issue a Notice indicating a person is no longer considered to be a routine violator. The Notice will be issued no more than 30 days after DOE has received documentation demonstrating that remediation is complete.

■ 11. Add § 429.154 to subpart C to read as follows:

§ 429.154 Remediation.

(a) Any party found to be in violation of the regional standards may remediate by replacing the noncompliant unit at cost to the violator; the end user cannot be charged for any costs of remediation.

(1) If a violator is unable to replace all noncompliant installations, then the Department may, in its discretion, consider the remediation complete if the violator satisfactorily demonstrates to the Department that it attempted to replace all noncompliant installations.

(2) The Department will scrutinize any "failed" attempts at replacement to ensure that there was indeed a good faith effort to complete remediation of the noncompliant unit.

(b) The violator must provide to DOE the serial number of any outdoor unit and/or indoor unit installed not in compliance with the applicable regional standard as well as the serial number(s) of the replacement unit(s) to be checked by the Department against warranty and other replacement claims.

(c) If the remediation is approved by the Department, then DOE will issue a Notice of Remediation and the violation will not count towards a finding of "routine violator".

■ 12. Add § 429.156 to subpart C to read as follows:

§ 429.156 Manufacturer and private labeler liability.

(a) In accordance with § 429.102, paragraphs (a)(10) and (c), manufacturers and private labelers are prohibited from selling central air conditioners and heat pumps to a routine violator.

(1) To avoid financial penalties, manufacturers and/or private labelers must cease sales to a routine violator within 3 business days from the date of issuance of a Notice of Finding of Routine Violation.

(2) If a Routine Violator files a Notice of Intent to Appeal pursuant to § 429.150, then a manufacturer and/or private labeler may assume the risk of selling central air conditioners to the Routine Violator during the pendency of the appeal.

(3) If the appeal of the Finding of Routine Violator is denied, then the manufacturer and/or private labeler may be fined in accordance with § 429.120, for sale of any units to a routine violator during the pendency of the appeal that do not meet the applicable regional standard.

(b) If a manufacturer and/or private labeler has knowledge of routine violation, then the manufacturer can be held liable for all sales that occurred after the date the manufacturer had knowledge of the routine violation. However, if the manufacturer and/or private labeler reports its suspicion of a routine violation to DOE within 15 days of receipt of such knowledge, then it will not be liable for product sold to the suspected routine violator prior to reporting the routine violation to DOE.

■ 13. Add § 429.158 to subpart C to read as follows:

§ 429.158 Product determined noncompliant with regional standards.

(a) If DOE determines a model of outdoor unit fails to meet the applicable regional standard(s) when tested in a combination certified by the same manufacturer, then the outdoor unit basic model will be deemed noncompliant with the regional standard(s). In accordance with § 429.102(c), the outdoor unit manufacturer and/or private labeler is liable for distribution of noncompliant units in commerce.

(b) If DOE determines a combination fails to meet the applicable regional standard(s) when tested in a combination certified by a manufacturer other than the outdoor unit manufacturer (*e.g.*, ICM), then that combination is deemed noncompliant with the regional standard(s). In accordance with § 429.102(c), the certifying manufacturer is liable for distribution of noncompliant units in commerce.

(c) All such units manufactured and distributed in commerce are presumed to have been installed in a region where they would not comply with the applicable energy conservation standard; however, a manufacturer and/or private labeler may demonstrate through installer records that individual units were installed in a region where the unit is compliant with the applicable standards.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 14. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 15. Amend § 430.2 by adding, in alphabetical order, new definitions for "contractor," "dealer," "distributor," and "installation of a central air conditioner" to read as follows:

§ 430.2 Definitions.

* * * * *

Contractor means a person (other than the manufacturer or distributor) who sells to and/or installs for an end user a central air conditioner subject to regional standards. The term "end user" means the entity that purchases or selects for purchase the central air conditioner. Some examples of typical "end users" are homeowners, building owners, building managers, and property developers.

* * * * *

Dealer means a type of contractor, generally with a relationship with one or more specific manufacturers.

* * * * *

Distributor means a person (other than a manufacturer or retailer) to whom a consumer appliance product is delivered or sold for purposes of distribution in commerce.

* * * * *

Installation of a central air conditioner means the connection of the refrigerant lines and/or electrical systems to make the central air conditioner operational.

* * * * *

■ 16. Section 430.32 is amended by revising paragraph (c) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(c) *Central air conditioners and heat pumps.* The energy conservation standards defined in terms of the heating seasonal performance factor are based on Region IV, the minimum standardized design heating requirement, and the provisions of 10 CFR 429.16.

(1) Each basic model of single-package central air conditioners and central air conditioning heat pumps and each individual combination of split-system central air conditioners and central air conditioning heat pumps manufactured on or after January 1, 2015, shall have a Seasonal Energy Efficiency Ratio and Heating Seasonal Performance Factor not less than:

Product class	Seasonal energy efficiency ratio (SEER)	Heating seasonal performance factor (HSPF)
(i) Split-system air conditioners	13	
(ii) Split-system heat pumps	14	8.2
(iii) Single-package air conditioners	14	
(iv) Single-package heat pumps	14	8.0
(v) Small-duct, high-velocity systems	12	7.2
(vi)(A) Space-constrained products—air conditioners	12	
(B) Space-constrained products—heat pumps	12	7.4

(2) In addition to meeting the applicable requirements in paragraph (c)(1) of this section, split-system air conditioners that are installed on or after January 1, 2015, in the States of Alabama, Arkansas, Delaware, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, or Virginia, or in the District of Columbia, must have a Seasonal Energy Efficiency Ratio (SEER) of 14 or higher. Any outdoor unit model that has a certified combination with a rating below 14 SEER cannot be installed in these States. The least efficient combination of each basic model must comply with this standard.

(3)(i) In addition to meeting the applicable requirements in paragraph (c)(1) of this section, split-system air conditioners and single-package air conditioners that are installed on or after January 1, 2015, in the States of Arizona, California, Nevada, or New Mexico must have a Seasonal Energy Efficiency Ratio (SEER) of 14 or higher and have an Energy Efficiency Ratio (EER) (at a standard rating of 95 °F dry bulb outdoor temperature) not less than the following:

Product class	Energy efficiency ratio (EER)
(A) Split-system rated cooling capacity less than 45,000 Btu/hr	12.2

Product class	Energy efficiency ratio (EER)
(B) Split-system rated cooling capacity equal to or greater than 45,000 Btu/hr	11.7
(C) Single-package systems	11.0

(ii) Any outdoor unit model that has a certified combination with a rating below 14 SEER or the applicable EER cannot be installed in this region. The least efficient combination of each basic model must comply with this standard.

(4) Each basic model of single-package central air conditioners and central air conditioning heat pumps and each individual combination of split-system central air conditioners and central air conditioning heat pumps manufactured on or after January 1, 2015, shall have an average off mode electrical power consumption not more than the following:

Product class	Average off mode power consumption $P_{W,OFF}$ (watts)
(i) Split-system air conditioners	30
(ii) Split-system heat pumps	33
(iii) Single-package air conditioners	30
(iv) Single-package heat pumps	33
(v) Small-duct, high-velocity systems	30
(vi) Space-constrained air conditioners	30
(vii) Space-constrained heat pumps	33

* * * * *

[FR Doc. 2016–16441 Filed 7–13–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–6136; Special Conditions No. 25–620–SC]

Special Conditions: American Airlines, Boeing 777–200 Series Airplanes; Dynamic Test Requirements for Single-Occupant Oblique (Side-Facing) Seats Equipped With Inflatable Lapbelts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Boeing 777–200 series airplane. This airplane, as modified by American Airlines, will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These airplanes will include single-occupant oblique seats with inflatable lapbelts requiring dynamic testing. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on American Airlines on July 14, 2016. We must receive your comments by August 29, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–6136 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/*, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John Shelden, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2785; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplanes.

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On November 3, 2015, American Airlines applied for a supplemental type certificate for installation of TSO–C39c-approved B/E Aerospace Super Diamond model oblique business-class passenger seats in Boeing Model 777–200 series airplanes. The Model 777–200 airplane, approved under type certificate no. T00001SE, is a transport-category, twin-engine jet airplane with a maximum capacity of 440 passengers and a maximum takeoff weight of 535,000 lbs.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, American Airlines must show that the Boeing Model 777–200 series airplane, as changed, continues to meet the applicable provisions of the regulations listed in type certificate no. T00001SE, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

In addition, the certification basis includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Boeing Model 777–200 series airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 777–200 series airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Boeing Model 777–200 series airplane will incorporate the following novel or unusual design features: Single-occupant oblique (side-facing) seats with inflatable lapbelts.

Discussion

Amendment 25–15 to part 25, dated October 24, 1967, introduced the subject of side-facing seats, and a requirement that each occupant in a side-facing seat must be protected from head injury by a safety belt and a cushioned rest that will support the arms, shoulders, head, and spine.

Subsequently, Amendment 25–20, dated April 23, 1969, clarified the definition of side-facing seats to require that each occupant of a seat that is positioned at more than an 18-degree angle to the vertical plane containing the airplane centerline must be protected from head injury by a safety belt and an energy-absorbing rest that supports the arms, shoulders, head, and spine; or by a safety belt and shoulder harness that prevents the head from contacting injurious objects. The FAA concluded that a maximum 18-degree angle would provide an adequate level of safety based on tests that were performed at the time, and thus adopted that standard.

Amendment 25–64, dated June 16, 1988, revised the emergency-landing conditions that must be considered in the design of the airplane. It revised the static-load conditions in § 25.561 and added a new § 25.562, requiring dynamic testing for all seats approved for occupancy during takeoff and landing. The intent was to provide an improved level of safety for occupants on transport-category airplanes. Because most seating on transport-category airplanes is forward-facing, the pass/fail criteria developed in Amendment 25–64 focused primarily on forward-facing seats. Therefore, the testing specified in the rule did not provide a complete measure of occupant injury in seats that are not forward-facing. However, § 25.785 does require that occupants of all seats that are occupied during taxi, takeoff, and landing not suffer serious injury as a result of the inertia forces specified in §§ 25.561 and 25.562.

To address recent research findings and accommodate commercial demand, the FAA developed a methodology to address all fully side-facing seats (*i.e.,* seats oriented in the airplane with the occupant facing 90 degrees to the direction of airplane travel) and has documented those requirements in a set of proposed new special conditions. The FAA issued policy statement PS–ANM–25–03–R1 on November 12, 2012, titled, “Technical Criteria for Approving Side-Facing Seats,” which conveys the injury criteria to be used in the special conditions. Some of those criteria are applicable to oblique seats but others are not, because the motion of an occupant in an oblique seat is different from the motion of an occupant in a fully side-facing seat during emergency landing conditions.

For shallower installation angles, the FAA has granted equivalent level of safety (ELOS) findings for oblique-seat installations on the premise that an occupant’s kinematics in an oblique seat during a forward impact would result in the body aligning with the impact direction. We predicted that the occupant response would be similar to an occupant of a forward-facing seat, and would produce a level of safety equivalent to that of a forward-facing seat. These ELOS findings were subject to many conditions that reflected the injury-evaluation criteria and mitigation strategies available at the time of issuance of the ELOS. However, review of dynamic test results for many of these oblique seat installations raised concerns that the premise was not correct. Potential injury mechanisms exist that are unique to oblique seats and are not mitigated by the ELOS self-alignment approach even if the occupant appears to respond similarly to a forward-facing seat.

These seats will be installed at a maximum angle of 30 degrees to the aircraft centerline and will include an inflatable lapbelt restraint system for occupant restraint and injury protection.

The airbag in the inflatable lapbelt is designed to limit occupant forward excursion in the event of an emergency landing condition. This reduces the potential for head injury, thereby reducing the Head Injury Criteria (HIC) measurement. The use of an inflatable airbag in this fashion is novel for commercial aviation.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 777–200 series airplane. Should American Airlines apply at a later date for a supplemental type certificate to modify any other model included on type certificate no. T00001SE, to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subject to the public-comment process with no substantive comments received. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 777–200 series airplanes modified by American Airlines.

In addition to the requirements of § 25.562:

1. Head-Injury Criteria

Compliance with § 25.562(c)(5) is required, except that, if the anthropomorphic test device (ATD) has no apparent contact with the seat/structure but has contact with an airbag, a HIC unlimited score in excess of 1000 is acceptable, provided the HIC15 score (calculated in accordance with 49 CFR 571.208) for that contact is less than 700.

2. Body-to-Wall/Furnishing Contact

If a seat is installed aft of structure (*e.g.* interior wall or furnishings) that does not provide a homogenous contact surface for the expected range of occupants and yaw angles, then additional analysis and/or tests may be required to demonstrate that the injury criteria are met for the area which an occupant could contact. For example, if an airbag device is present, different yaw angles could result in different airbag-device performance, and additional analysis or separate tests may be necessary to evaluate performance.

3. Neck Injury Criteria

The seating system must protect the occupant from experiencing serious neck injury. If an airbag device is present, the assessment of neck injury must be conducted with the airbag device activated, unless there is reason to also consider that the neck-injury potential would be higher for impacts below the airbag-device deployment threshold.

a. The N_{ij} (calculated in accordance with 49 CFR 571.208) must be below 1.0, where $N_{ij} = F_z/F_{zc} + M_y/M_{yc}$, and N_{ij} critical values are:

i. F_{zc} = 1530 lb for tension
ii. F_{zc} = 1385 lb for compression
iii. M_{yc} = 229 lb-ft in flexion
iv. M_{yc} = 100 lb-ft in extension

b. In addition, peak upper-neck F_z must be below 937 lb in tension and 899 lb in compression.

c. Rotation of the head about its vertical axis, relative to the torso, is limited to 105 degrees in either direction from forward-facing.

d. The neck must not impact any surface that would produce concentrated loading on the neck.

4. Spine and Torso Injury Criteria

a. The lumbar spine tension (Fz) cannot exceed 1200 lb.

b. Significant concentrated loading on the occupant's spine, in the area between the pelvis and shoulders during impact, including rebound, is not acceptable. During this type of contact, the interval for any rearward (X direction) acceleration exceeding 20g must be less than 3 milliseconds as measured by the thoracic instrumentation specified in 49 CFR part 572, subpart E, filtered in accordance with SAE International (SAE) Recommended Practice J211/1, "Instrumentation for Impact Test—Part 1—Electronic Instrumentation."

c. The occupant must not interact with the armrest or other seat components in any manner significantly different than would be expected for a forward-facing seat installation.

5. Pelvis Criteria

Any part of the load-bearing portion of the bottom of the ATD pelvis must not translate beyond the edges of the seat bottom seat-cushion supporting structure.

6. Femur Criteria

Axial rotation of the upper leg (about the z-axis of the femur per SAE Recommended Practice J211/1) must be limited to 35 degrees from the nominal seated position. Evaluation during rebound does not need to be considered.

7. ATD and Test Conditions

Longitudinal tests conducted to measure the injury criteria above must be performed with the FAA Hybrid III ATD, as described in SAE 1999–01–1609, "A Lumbar Spine Modification to the Hybrid III ATD for Aircraft Seat Tests," V. Gowdy, et al. (1999). The tests must be conducted with an undeformed floor, at the most-critical yaw cases for injury, and with all lateral structural supports (*e.g.*, armrests or walls) installed.

Note: In addition to these special conditions, the inflatable lapbelts must meet the criteria of special conditions no. 25–187A–SC, titled, "Boeing Model 777 Series Airplanes; Seats with Inflatable Lapbelts."

Issued in Renton, Washington, on July 7, 2016.

Michael Kaszycki,

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–16639 Filed 7–13–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–4429; Airspace Docket No. 16–ASW–8]

Amendment of Class E Airspace for the Following Louisiana Towns; De Quincy, LA; Minden, LA; Slidell, LA; and Revocation of Class E Airspace; Homer, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at De Quincy Industrial Airpark, De Quincy, LA; Minden Airport, Minden, LA; and Slidell, Airport, Slidell, LA. The decommissioning of non-directional radio beacons (NDB) and/or cancellation of NDB approaches due to advances in Global Positioning System (GPS) capabilities, and implementation of area navigation (RNAV) procedures have made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at these airports. This action also removes Class E airspace extending upward from 700 feet above the surface at Homer Municipal Airport, Homer, LA, as controlled airspace is no longer needed. Additionally, the name of Minden Airport (formerly Minden-Webster Airport) and the geographic coordinates at De Quincy Industrial Airpark, Minden Airport, and Slidell Airport are being adjusted to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, September 15, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation

Administration, 800 Independence Avenue SW., Washington, DC, 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at De Quincy Industrial Airpark, De Quincy, LA; Homer Municipal Airport, Homer, LA; Minden Airport, Minden, LA; and Slidell, Airport, Slidell, LA.

History

On April 13, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) (81 FR 21774), Docket No. FAA–2016–4429, to modify Class E airspace extending upward from 700 feet above the surface at De Quincy Industrial Airpark, De Quincy, LA; Homer Municipal Airport, Homer, LA; Minden Airport, Minden, LA; and Slidell, Airport, Slidell, LA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Subsequent to publication, the FAA found that Minden-Webster Airport had been changed to Minden Airport and is noted as such in this rule.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace extending upward from 700 feet above the surface within a 7.5-mile radius of De Quincy Industrial Airpark, De Quincy, LA; within a 6.5-mile radius of Minden Airport, Minden, LA; and within a 6.5-mile radius of Slidell Airport, Slidell, LA, with segments extending from the 6.5-mile radius to 9.2 miles north, and 9 miles south of the airport. Airspace reconfiguration is necessary due to the decommissioning of NDBs, cancellation of NDB approaches, and implementation of RNAV procedures at the above airports. The Class E airspace area extending upward from 700 feet above the surface within a 6.8-mile radius of Homer Municipal Airport, Homer, LA, is being removed as controlled airspace is no longer needed. Additionally, the name of Minden Airport (formerly Minden-Webster Airport) and the geographic coordinates at De Quincy Industrial Airpark, Minden Airport, and Slidell Airport are being adjusted to coincide with the FAA's aeronautical database. All modifications to the Class E airspace are in accordance with airspace requirements specified in FAA Joint Order 7400.2K, Procedures for Handling Airspace Matters. Controlled airspace is necessary for the safety and management of standard instrument approach procedures for IFR operations at the airports.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71 —DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 Amended

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW LA E5 De Quincy, LA [Amended]

De Quincy Industrial Airpark, LA
(Lat. 30°26′28″ N., long. 93°28′25″ W.)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of De Quincy Industrial Airpark.

* * * * *

ASW LA E5 Homer, LA [Removed]

* * * * *

ASW LA E5 Minden, LA [Amended]

Minden Airport, LA
(Lat. 32°38′46″ N., long. 93°17′53″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Minden Airport.

* * * * *

ASW LA E5 Slidell, LA [Amended]

Slidell Airport, LA
(Lat. 30°20′47″ N., long. 89°49′15″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Slidell Airport, and within 4.0 miles each side of the 360° bearing from the airport extending from the 6.5-mile radius to 9.2 miles north of the airport, and within 4.0 miles each side of the 180° bearing from the airport extending from the 6.5-mile radius to 9.0 miles south of the airport.

Issued in Fort Worth, Texas, on June 27, 2016.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–16383 Filed 7–13–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 14 and 20

[Docket No. FDA–2015–N–2103]

Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Agency's regulations by removing certain regulations that include obsolete references. FDA is taking this action to improve the accuracy of the regulations.

DATES: This rule is effective July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 2016 (81 FR 7445), FDA published a final rule entitled "Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972" (February 2016 final rule). In the February 2016 final rule, FDA, in part, removed § 601.25 (21 CFR 601.25), which prescribed procedures for FDA's review of biological products licensed before July 1, 1972.

Under § 14.1(a)(2) (21 CFR 14.1(a)(2)), specific provisions are provided for a matter that is subject to a hearing before an advisory committee. Under § 20.100(c) (21 CFR 20.100(c)), in addition to the provisions of 21 CFR part 20, rules on the availability of specific categories of FDA records are established by regulations under Chapter I of Title 21 of the Code of Federal Regulations. Sections 14.1(a)(2)(v) and 20.100(c)(22) include a reference to § 601.25. In the February 2016 final rule, FDA inadvertently did not remove these sections (§§ 14.1(a)(2)(v) and 20.100(c)(22)) that referenced § 601.25. Accordingly, FDA is removing and reserving §§ 14.1(a)(2)(v) and 20.100(c)(22).

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment is unnecessary because the amendments to the regulations are nonsubstantive.

List of Subjects

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 14 and 20 are amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

§ 14.1 [Amended]

■ 2. In § 14.1, remove and reserve paragraph (a)(2)(v).

PART 20—PUBLIC INFORMATION

■ 3. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

§ 20.100 [Amended]

■ 4. In § 20.100, remove and reserve paragraph (c)(22).

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16637 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9778]

RIN 1545–BM24

Participation of a Person Described in Section 6103(n) in a Summons Interview Under Section 7602(a)(2) of the Internal Revenue Code

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations modifying regulations under section 7602(a) of the Internal Revenue Code relating to administrative summonses. Specifically, these final regulations clarify that persons with whom the IRS or the Office of Chief Counsel (Chief Counsel) contracts for services described in section 6103(n) and its implementing regulations may be included as persons designated to receive summoned books, papers, records, or other data and, in the presence and under the guidance of an IRS officer or employee, participate fully in the interview of a witness summoned by the IRS to provide testimony under oath. These regulations may affect taxpayers, a taxpayer's officers or employees, and any third party who is served with a summons, as well as any other person entitled to notice of a summons.

DATES: *Effective Date:* These regulations are effective on July 14, 2016.

Applicability Date: For date of applicability, see § 301.7602–1(d).

FOR FURTHER INFORMATION CONTACT: William V. Spatz at (202) 317–5461 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

These final regulations amend Procedure and Administration Regulations (26 CFR part 301) under section 7602 of the Internal Revenue Code. These final regulations clarify that persons described in section 6103(n) and Treas. Reg. § 301.6103(n)–1(a) with whom the IRS or Chief Counsel contracts for services—such as outside economists, engineers, consultants, or attorneys—may receive books, papers, records, or other data summoned by the IRS and, in the presence and under the guidance of an IRS officer or employee, participate fully in the interview of a person who the IRS has summoned as a witness to provide testimony under oath. On June 18, 2014, temporary regulations (TD 9669) regarding participation in a summons interview of a person described in section 6103(n) were published in the **Federal Register** (79 FR 34625). A notice of proposed rulemaking (REG–121542–14) cross-referencing the temporary regulations was published in the **Federal Register** (79 FR 34668) the same day.

No public hearing was requested or held. The Internal Revenue Service received two comments to the proposed regulations. One comment recommends that the regulations be revised to remove the provision permitting a contractor to question a witness under oath or to ask a witness's representative to clarify an objection or assertion of privilege. The other comment recommends that the proposed and temporary regulations be withdrawn. After consideration of both comments, the sole amendment to the proposed regulations is to replace the word "examine" with "review" in the phrase describing what contractors may do with books, papers, records, or other data received by the IRS under a summons. This revision clarifies that the regulations do not permit contractors to direct examinations (that is, audits) of a taxpayer's return. Accordingly, the proposed regulations are adopted as amended by this Treasury decision, and the corresponding temporary regulations are removed.

Explanation and Summary of Comments

1. Potential for IRS Loss of Control Over Interview

One comment raises concerns about how the regulations would operate in practice. This comment states that turning the questioning of a witness over to a third-party contractor may cause the IRS officer or employee in charge of the interview to lose control of the interview. The comment further states that having multiple persons "on the record"—an IRS officer or employee, a contractor, a witness, and a representative of the witness—may lead to a cluttered, incomprehensible transcript of the interview. To address these concerns, the comment suggests that instead of having the contractor question the witness directly, the IRS officer or employee should announce to the court reporter that he or she needs a moment to confer with the contractor, and after consultation ask to go back on the record to resume questioning.

These concerns are unfounded. When the IRS hires a contractor to assist the IRS in reviewing books and records, analyzing data, or receiving sworn testimony from a summoned witness, the IRS determines what information will be requested via a summons and who the summons will request to testify. An IRS officer or employee is present during the interview and remains in charge of the interview. A contractor asking questions does not present any additional difficulties for the IRS officer or employee in retaining control of that interview. Rather, the IRS officer or employee in charge of the interview may be in a better position to maintain control of the overall interview if someone else is asking the questions. The IRS officer or employee always has the ability to ask the court reporter to go off the record to confer with the contractor, if necessary.

Further, since 2002, § 301.7602–1(b)(1) has provided that a summoned witness may be required to appear before "one or more" IRS officers or employees to give testimony, including Chief Counsel attorneys. During this time, the IRS experience with multiple persons asking questions of summoned persons has not resulted in cluttered interview transcripts as compared to those transcripts in which only one person from the IRS asks a witness questions. Instead, the IRS has generally found that allowing multiple IRS persons to question a summoned witness results in more thorough and complete coverage of the appropriate interview topics. This is particularly true when a person asking questions for the IRS has the chance to focus questions on particular subject areas with which the questioner is most familiar. Furthermore, the IRS has found that significant value is also added when multiple persons have the opportunity to ask questions to address gaps in prior questioning or clarify answers by a witness.

Accordingly, for the reasons discussed above, the proposed regulations have not been amended as suggested by this comment.

2. Statutory Authority for an Outside Contractor To Question a Summoned Witness

Both comments state section 7602 does not authorize a contractor to question a witness during an IRS summons interview. Specifically, the comments state that the regulations improperly delegate to the contractor the Secretary's authority under section 7602(a)(3) to take testimony under oath. According to one of the comments, because section 7701(a)(11)(B) defines the term "Secretary" to include a delegate, and section 7701(a)(12)(A) defines a "delegate" of the Secretary, in part, as a duly authorized "officer, employee or agency of the Treasury Department," the regulations improperly attempt to treat a "third party agent" (a contractor under section 6103(n)) as an "agency of the Treasury Department." The other comment adds that this type of treatment of a contractor would be unprecedented under various IRS Delegation Orders and Internal Revenue Manual provisions and that a statutory authorization is required for "such delegation." Both comments state that section 6306, regarding the IRS's use of private collection agencies to perform certain tax collection functions, was an example of such authorization by statute.

Further, both comments question whether under the regulations inherently governmental functions will continue to be performed by IRS officers or employees, and state that reference to this in the preamble to the temporary regulations was included to allay potential concerns about improper delegation. The comment also asserts that taking testimony by asking questions, reviewing books or papers, and analyzing other data, as allowed by the regulations, is inherently governmental. In support of this, the comment states that when contractors ask questions that taxpayers are compelled to answer under oath, the contractor is deciding what information must be produced by the taxpayer. The comment asserts that it is clear that questioning a witness under oath and with compulsion, or directing counsel for a witness to clarify an objection or assertion of privilege, in an extra-judicial governmental investigation such as an IRS audit is inherently governmental. This comment states that the fact that a contractor's participation in a summons interview will only be done in the presence and under the guidance of an IRS officer or employee suggests that participation in a summons interview is inherently governmental.

These comments state further that the reference to § 301.7602–2(c)(1)(i)(B) and (c)(1)(ii) Example 2 in the preamble to the temporary regulations means that the regulations are delegating authority under section 7602(a) to the contractor.

The IRS has broad information gathering authority under section 7602(a). See *United States* v. *Arthur Young & Co.,* 465 U.S. 805, 816 (1984). Section 7602(a) provides that, for the purpose of ascertaining the correctness of any return, making a return where none has been made, or determining the liability of any person for any internal revenue tax, the Secretary (and the IRS as the Secretary's delegate) is authorized to examine books and records, issue summonses seeking documents and testimony, and take testimony from witnesses under oath. When a contractor assists the IRS in gathering facts by reviewing books and records or asking questions of a witness during a summons interview, the contractor is merely assisting in carrying out the powers granted to the Secretary. Nothing in section 7602(a) prohibits participation by a contractor in a summons interview, nor does it prescribe procedures that the IRS must follow during the summons interview.

Moreover, nothing in these regulations delegates authority under section 7602(a). The IRS's authority to engage contractors to assist with fact gathering has always existed under section 7602, and the comments acknowledge this authority. For instance, the comment addressing the impact of multiple questioners on the clarity of the transcribed record of the summons interview suggests as an alternative that the contractor provide the IRS with the questions to ask. Given that the commentators acknowledge that the IRS is authorized to have a contractor communicate the question off the record to the IRS, it seems implausible that having the contractor actually ask the question on the record, in the presence of and under the supervision of the IRS, is substantively different.

Section 6306, dealing with qualified tax collection contracts, does not support the contention in the comments that congressional action is required to engage a contractor to perform services for the IRS. Long before section 6306 was added to the Code in 2004, the IRS collection function had contracted with private persons (*for example,* locksmiths, tow truck drivers, storage facilities, property appraisers and auctioneers) for tax administration purposes to facilitate IRS seizures of property by levy and IRS sales of such property, pursuant to the statutory powers conferred on the Secretary by sections 6301, 6331, and 6335. In fiscal years 1996 and 1997, without making any modifications to the Code, Congress earmarked $13 million for the IRS to test the use of private debt collection companies. In 2004, rather than say it was authorizing the IRS to enter into collection agreements with outside contractors to assist the IRS in collecting tax debts, Congress instead said in section 6306(a) that "[n]othing in any provision of law shall be construed to prevent the Secretary from entering into a qualified tax collection contract." Therefore, section 6306 was a congressional clarification of the IRS's existing authority to engage outside contractors to assist with collection. Accordingly, contrary to the comments' assertions, no explicit congressional authorization was needed to permit the IRS to hire outside contractors to assist in the collection of taxes, a role outside contractors had been playing for years prior to enactment of section 6306. As a result, enactment of section 6306 does not support the contention in the comments that having a contractor ask questions during a summons interview is inconsistent with authority under section 7602.

The comments are also incorrect that the regulations include an improper delegation to perform certain examination functions. One comment assumes that the role of questioner must be accompanied by the power to compel the witness to answer under oath. That is not accurate. While the contractor will ask questions during a summons interview, an IRS officer or employee will determine whether the questions must be answered by pursuing judicial enforcement. Only if an IRS officer or employee pursues the matter by seeking judicial enforcement can a witness be compelled to answer the question asked by the contractor. Similarly, a contractor can ask counsel for a witness to clarify an objection or assertion of privilege, but only an IRS officer or employee can pursue resolution of the claim of privilege by seeking judicial enforcement. Accordingly, the comment incorrectly equates the act of compelling a witness to answer a question asked with the mere act of asking the question. Further, the Federal Activities Inventory Reform Act of 1998, Public Law 105–270 (31 U.S.C. 501 Note (FAIR Act)), defines "inherently governmental function" as "a function that is so intimately related to the public interest as to require performance by Federal Government employees." FAIR Act section 5(2)(A). Inherently governmental functions include activities that require "the exercise of discretion in applying Federal Government authority," including "the interpretation and execution of the laws of the United States so as . . . to bind the United States to take or not to take some action." *Id.* at section 5(2)(B)(i). However, Congress further specified in FAIR Act section 5(2)(C)(i) that an inherently governmental function does *not* normally include "gathering information for or providing advice, opinions, recommendations, or ideas to Federal Government officials."

In 2009, Congress further directed the Office of Management and Budget (OMB) to refine the definition of "inherently governmental function" applicable to all agencies and provide guidance to improve internal agency management of functions that are inherently governmental. Public Law 110–417, section 321. Toward these ends, and after notice and comment, OMB's Office of Federal Procurement Policy (OFPP) issued its Policy Letter 11–01 on September 12, 2011. 76 FR 56227. The Policy Letter clarified the "discretion" that a contractor may appropriately exercise as the circumstances "where the contractor does not have the authority to decide on the overall course of action, but is tasked to develop options or implement a course of action, and the agency official has the ability to override the contractor's action." *Id.,* at section 5–1(a)(1)(ii)(B), 76 FR at 56237. The Policy Letter further explains that "contractors routinely, and properly, exercise discretion in performing functions for the Federal Government when, providing advice, opinions, or recommended actions, emphasizing certain conclusions, and . . . deciding what techniques and procedures to employ, whether and whom to consult, [and] what research alternatives to explore given the scope of the contract." *Id.,* 76 FR at 56237–38. The Policy Letter recognizes that in addition to functions that are inherently governmental, there are also many functions closely associated with inherently governmental functions. The Policy Letter cautions that when a contractor function is closely associated with an inherently governmental one, the agency should "limit or guide the contractor's exercise of discretion," by "establishing in advance a process for subjecting the contractor's discretionary decisions and conduct to meaningful oversight and, whenever necessary, final approval by an agency official." *Id.*, at section 5–2(a)(4)(ii) and Appendix C, section (1)(ii), 76 FR at 56238–39 and 56241–42.

Accordingly, the preamble to the temporary regulations described the inherently governmental functions associated with section 7602(a) as including the ultimate decisions to issue a summons, whom to summon, what information must be produced or who will be required to provide testimony, as well as issuing the summons. The final decision to issue an IRS summons may "bind the United States to take or not take some action," within the meaning of the FAIR Act section 5(2)(B)(i). For example, serving an IRS summons pursuant to sections 7609(f) and (g) requires prior court approval, and IRS summonses issued for an examination purpose to third parties generally expose the United States to a court action the taxpayer may commence to quash a summons under section 7609(b)(2) or obligate the IRS to pay certain search and reproduction costs incurred by the summoned witness under section 7610. The final decision to include or not include certain document or testimony requests in an IRS summons also limits going forward what information or documents the IRS may ask a court to require a witness to produce in any future summons enforcement proceeding regarding that summons. The final decision to seek judicial enforcement of an IRS summons pursuant to sections 7402(b) and 7604 is also an inherently governmental function. These inherently governmental actions associated with issuing or seeking to enforce an IRS summons will continue to be performed by IRS officers and employees under these regulations.

As discussed above, pursuant to these regulations, contractors may assist IRS officers and employees when the IRS has summoned a witness, by receiving and reviewing books, papers, records, or other data produced in compliance with a summons and, in the presence and under the guidance of an IRS officer or employee, ask questions in the interview of the summoned witness. The contractor's assistance to the IRS officer or employee presiding over a summons interview is closely associated with the inherently governmental summons functions performed by an IRS employee, within the meaning of OFPP Policy Letter 11–01, without crossing the line into the performance of inherently governmental functions. A contractor participating fully in a summons interview will not, for example, be permitted to bind or otherwise disadvantage the IRS by making any unauthorized, premature statements that the summoned party has produced all of the summoned information or has fully answered all of the questions asked by the IRS in the interview. Similarly, the contractor has no authority to commit the IRS to pursue judicial enforcement of a summons for any documents or answers to questions that a witness failed to provide.

The contractor's "discretion" in pursuing any potentially relevant line of questioning in a summons interview is permissible under Policy Letter 11–01 standards because the contractor will not have the authority to decide on the overall course of action adopted by the IRS with respect to the summons interview. The IRS officer or employee presiding over IRS receipt of documents and evidence from the summoned witness will also be present for any questioning pursued by the contractor and will have the ability to override the contractor's actions, if necessary and appropriate. Rather than proving that a contractor would be performing an inherently governmental function under these regulations, the additional safeguards the comment points to—that a contractor's participation in a summons interview will only be done in the presence and under the guidance of an IRS officer or employee—show the IRS heeded the instructions of Policy Letter 11–01 to establish a process for subjecting the contractor's discretionary decisions and conduct under these regulations to meaningful IRS oversight.

The comments incorrectly interpret the purpose of the reference in the preamble of the temporary regulations to § 301.7602–2(c)(1)(i)(B) and (c)(1)(ii) Example 2. The purpose of referencing that regulation, which implements the provisions of section 7602(c) (requiring notice of third party contacts) in the case of a section 6103(n) contractor, was instead intended to highlight the fact that the IRS had been allowing contractors, under the guidance of an IRS officer or employee, to hold discussions and ask questions of witnesses for many years and that the proposed regulations were in the nature of a clarification. The purpose was not to demonstrate that the IRS is delegating authority to contractors as the comments incorrectly state.

Therefore, for the reasons above, Treasury and the IRS disagree with the comments' assertion that the regulations improperly delegate authority under section 7602. The statute permits section 6103(n) contractors to receive books, papers, records, or other data summoned by the IRS and, in the presence and under the guidance of an IRS officer or employee, participate fully in the interview of a person who the IRS has summoned as a witness to provide testimony under oath.

3. Confidential Taxpayer Information Provided to a Contractor

One of the comments suggests that the proposed regulations raise issues relating to confidentiality of taxpayer information. First, the comment states that the regulations place confidential taxpayer information unnecessarily at risk of unauthorized disclosure under section 6103. According to the comment, this is because placing taxpayer information in the hands of outside contractors under section 6103(n) increases the risk of misuse and unlawful disclosure because outside contractors are not subject to the same rules of conduct as IRS employees and may have loyalties to other clients besides the IRS and the public fisc.

Next, the comment questions whether the disclosure of confidential information to outside counsel is permitted under section 6103(n). The comment explains that in 1990 the phrase "other services" was added to section 6103(n) to cover outside experts, in part, because these experts are objective and the IRS is not. The comment continues that outside counsel, as an advocate, is not objective and, therefore, is not covered by the phrase "other services" in section 6103(n).

Finally, the comment states that the IRS has failed to demonstrate that government employees cannot effectively and more appropriately perform the function contemplated by the temporary regulations.

These comments do not address the clarification made by the proposed and temporary regulations (that is, that section 6103(n) contractors may be present at summons interviews, ask questions at a summons interview, and review summoned books, papers, records, or other data). Further, the comments do not explain why the proposed regulations place confidential taxpayer information at risk of unauthorized disclosure at all. Rather, these comments address disclosure to experts under section 6103(n), which is not the subject of these regulations. Therefore, the comments do not address issues under the regulations.

Regardless of the relevance of the comments to these regulations, the IRS takes protection of the confidentiality of taxpayer information seriously and will not disclose taxpayer information unless authorized under the law. "Return information" and "taxpayer return information" are in general broadly defined in sections 6103(b)(2) and (b)(3), as including information concerning a taxpayer's identity, the nature, source or amount of his income, payments, receipts, deductions, exemptions, credits, assets, liabilities, net worth, tax liabilities, tax withheld, owed, or paid, whether the taxpayer is being or will be examined or investigated, to the extent such information is filed with or furnished to the IRS by or on behalf of the taxpayer to whom such information relates.

Section 6103(n) authorizes the IRS to disclose confidential taxpayer information to persons who provide services to the IRS, including outside experts. The legislative history of section 6103(n) indicates that Congress added the words "other services" in 1990 to ensure that persons who provide services to the IRS, such as expert witnesses, and to whom the IRS discloses returns and return information pursuant to section 6103, would clearly be subject to the same confidentiality standards and penalties for unauthorized disclosure as are IRS employees.

In sections 7431, 7213, and 7213A, Congress created parallel civil and criminal deterrents for outside contractors (to those applicable to IRS employees) to punish any misuse of taxpayer return information through unlawful inspection or unlawful disclosure of such information. Specifically, section 7431(a)(2) authorizes taxpayers to file the same type of civil action for damages against an IRS contractor for knowingly, or by reason of negligence, making any unauthorized inspection or unauthorized disclosure of taxpayer return information, as may be filed against the United States for the same type of conduct committed by any officer or employee of the United States. Similarly, in sections 7213(a)(1) and 7213A(a)(1)(B) (by references to persons described in section 6103(n)), Congress made it a crime punishable by up to five years or up to one year of imprisonment, plus a fine, for an IRS contractor to willfully make an unauthorized disclosure or an unauthorized inspection of taxpayer return information, respectively. If an IRS officer or employee is convicted under sections 7213 or 7213A, such person will also be dismissed or discharged from Federal employment. Before any conviction, if the IRS determines that a contractor has violated its taxpayer return information disclosure obligations under its contract, the IRS may also suspend or terminate the contract, pursuant to § 301.6103(n)–1(e)(4)(iii). Moreover, § 301.6103(n)–1(e)(4) provides further safeguards against unlawful disclosures or inspections of taxpayer return information by contractors.

Finally, it is unclear what connection the comment is making between protecting confidentiality of taxpayer information and objectivity of the section 6103(n) contractor. First, there is no obligation under section 6103(n) or the regulations thereunder for a contractor under section 6103(n) to be objective. Second, whether a contractor is objective has no relation to whether the contractor has an obligation to protect confidential taxpayer information from disclosure or the contractor's ability to do so.

For these reasons, the Treasury and the IRS disagree that the regulations place confidential taxpayer information unnecessarily at risk of unauthorized disclosure.

4. Potential Litigation Costs To Enforce the Regulation

One comment states that including a provision to allow an IRS contractor in a summons interview to question a witness under oath in the final regulations would result in time-consuming and costly litigation for the IRS, taxpayers, third party witnesses, and the courts, and that these costs would outweigh the potential benefits to the IRS from a contractor directly questioning a summoned witness under oath. The comment does not indicate how it came to this conclusion, nor does it provide any support for its concern.

The IRS makes the decision of whether to issue a summons or to pursue summons enforcement actions on a case-by-case basis, analyzing each situation in the light of its particular facts and weighing the desired information against the tax liability involved, the time and expense of obtaining the records, and the adverse effect on voluntary compliance by others if the enforcement actions are not successful. A contractor's participation in a summons interview does not factor into the IRS's decision to request the Department of Justice to institute enforcement action or lead the taxpayer ultimately to file a deficiency action in the United States Tax Court or a refund claim in a United States District Court or the Court of Federal Claims. As a practical matter, the IRS will likely hire contractors to assist in the factual development of an examination only in significant cases. These are cases in which litigation over summons enforcement is already likely to occur if the IRS examination team faces resistance from taxpayers to providing requested information. Accordingly, there should not be considerably more litigation as a result of these final regulations. Moreover, when there is summons enforcement litigation, it will be because the IRS has determined that such litigation is in the best interest of tax administration.

5. Procedural Concerns With the Issuance of the Temporary Regulations

One of the comments states that the temporary regulations were not issued in accordance with the Administrative Procedure Act (APA). The temporary regulations were promulgated in full compliance with the APA. In addition, this document finalizes proposed regulations contained in a notice of proposed rulemaking that cross-referenced the temporary regulations. The proposed regulations were also promulgated in full compliance with the APA. Because these final regulations adopt the proposed regulations, it is not necessary to address concerns regarding procedural issues relating to promulgation of the temporary regulations.

Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. The IRS has determined that sections 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) do not apply to these regulations and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comments on its impact on small business, and no comments were received.

Drafting Information

The principal author of these final regulations is William V. Spatz of the Office of Associate Chief Counsel

(Procedure and Administration). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.7602–1T [Removed]

■ **Par. 2.** Section 301.7602–1T is removed.

■ **Par. 3.** Section 301.7602–1 is amended by adding paragraph (b)(3) and revising paragraph (d) to read as follows:

§ 301.7602–1 Examination of books and witnesses.

* * * * *

(b)(3) *Participation of a person described in section 6103(n).* For purposes of this paragraph (b), a person authorized to receive returns or return information under section 6103(n) and § 301.6103(n)–1(a) of the regulations may receive and review books, papers, records, or other data produced in compliance with a summons and, in the presence and under the guidance of an IRS officer or employee, participate fully in the interview of a witness summoned by the IRS to provide testimony under oath. Fully participating in an interview includes, but is not limited to, receipt, review, and use of summoned books, papers, records, or other data; being present during summons interviews; questioning the person providing testimony under oath; and asking a summoned person's representative to clarify an objection or assertion of privilege.

* * * * *

(d) *Applicability date.* This section is applicable after September 3, 1982, except for paragraphs (b)(1) and (2) of this section which are applicable on and after April 1, 2005 and paragraph (b)(3) of this section which applies to summons interviews conducted on or after July 14, 2016. For rules under paragraphs (b)(1) and (2) that are applicable to summonses issued on or after September 10, 2002 or under paragraph (b)(3) that are applicable to summons interviews conducted on or after June 18, 2014, see 26 CFR 301.7602–1T (revised as of April 1, 2016).

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: May 27, 2016.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–16606 Filed 7–12–16; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0267]

RIN 1625–AA00

Safety Zone; Tall Ships Challenge Great Lakes 2016, Fairport Harbor, OH, Bay City, MI, Chicago, IL, Green Bay, WI, Duluth, MN, Erie, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is creating temporary safety zones around each tall ship visiting the Great Lakes during the Tall Ships Challenge 2016 race series. These safety zones will provide for the regulation of vessel traffic in the vicinity of each tall ship in the navigable waters of the United States. The Coast Guard is taking this action to safeguard participants and spectators from the hazards associated with the limited maneuverability of these tall ships and to ensure public safety during tall ships events.

DATES: This rule is effective without actual notice from July 14, 2016 through 12:01 a.m. on September 12, 2016. For the purposes of enforcement, actual notice will be used from 12:01 a.m. July 6, 2016 through July 14, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0267 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mark Bobal, Ninth District Inspections and Investigations Branch, Passenger Vessel Safety Specialist, U.S. Coast Guard; telephone 216–902–6052, email *Mark.D.Bobal@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

During the Tall Ships Challenge Great Lakes 2016, tall ships will be participating in parades and then mooring in the harbors of Fairport Harbor, OH, Bay City, MI, Chicago, IL, Green Bay, WI, Duluth, MN, Erie, PA. This is a tri-annual event that teaches character building and leadership through sail training. The Tall Ships event seeks to educate the public about both the historical aspects of sailing ships as well as their current use as training vessels for students. Tall ships are large, traditionally-rigged sailing vessels. The event will consist of festivals at each port of call, sail training cruises, tall ship parades, and races between the ports. More information regarding the Tall Ships Challenge 2016 and the participating vessels can be found at *http://www.sailtraining.org/tallships/2016greatlakes/TSC2016index.php*

The Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Tall Ships Challenge Great Lakes 2016, Fairport Harbor, OH, Bay City, MI, Chicago, IL, Green Bay, WI, Duluth, MN, Erie, PA (USCG–2016–0267, 81 FR 26767, May 4, 2016). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related. During the comment period that ended June 3, 2016, we received one comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Ninth District Commander has determined that potential hazards associated with tall ships operating in crowded harbors in close proximity to spectator craft necessitate a safety zone. The purpose of this rule is to ensure the safety of all vessels during the Tall Ship events.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comments on our NPRM published May 4, 2016. The comment was directed at a rule pertaining to a fireworks show during a university graduation and did not apply to this rule. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 12:01 a.m. July 6, 2016, that is established around each Tall Ship participating in this event. The safety zone covers all navigable waters within 100 yards of a tall ship in the Great Lakes. The duration of the zone is intended to ensure the safety of vessels and these navigable waters during the 2016 Tall Ships Challenge. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. If the tall ships are operating in a confined area such as a small harbor and there is not adequate room for vessels to stay out of the safety zone because of a lack of navigable water, then vessels will be permitted to operate within the safety zone and shall travel at the minimum speed necessary to maintain a safe course. The navigation rules apply at all times within the safety zone. The safety zone terminates at 12:01 a.m. on September 12, 2016.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone. Commercial traffic does not typically come within the boundaries of the safety zone, and would be permitted to pass through the safety zone in accordance with the rule. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit vessels from passing within 100 yards of a tall ship without coming to a slow speed. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a

Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0073 to read as follows:

§ 165.T09–0073 Safety Zone; Tall Ships Challenge Great Lakes 2016; Fairport Harbor, OH, Bay City, MI, Chicago, IL, Green Bay, WI, Sturgeon Bay, WI, Duluth, MN, Erie, PA.

(a) *Definitions.* The following definitions apply to this section:

(1) Navigation Rules means the Navigation Rules, International and Inland (See, 1972 COLREGS and 33 U.S.C. 2001 *et seq.*).

(2) Official Patrol means those persons designated by Captain of the Port Buffalo, Detroit, Sault Ste. Marie, Duluth and Lake Michigan to monitor a tall ship safety zone, permit entry into the zone, give legally enforceable orders to persons or vessels within the zone, and take other actions authorized by the cognizant Captain of the Port.

(3) Public Vessel means vessels owned, chartered, or operated by the United States or by a State or political subdivision thereof.

(4) Tall Ship means any sailing vessel participating in the Tall Ships Challenge 2016 in the Great Lakes.

(b) *Location.* The following areas are safety zones: all navigable waters of the United States located in the Ninth Coast Guard District within a 100 yard radius of any tall ship.

(c) *Regulations.* (1) No person or vessel is allowed within the safety zone unless authorized by the cognizant Captain of the Port, their designated representative, or the on-scene official patrol.

(2) Persons or vessels operating within a confined harbor or channel, where there is not sufficient navigable water outside of the safety zone to safely maneuver are allowed to operate within the safety zone and shall travel at the minimum speed necessary to maintain a safe course. Vessels operating within the safety zone shall not come within 25 yards of a tall ship unless authorized by the cognizant Captain of the Port, their designated representative, or the on-scene official patrol.

(3) When a tall ship approaches any vessel that is moored or anchored, the stationary vessel must stay moored or anchored while it remains within the tall ship's safety zone unless ordered by or given permission from the cognizant Captain of the Port, their designated representative, or the on-scene official patrol to do otherwise.

(d) *Effective period.* This rule is effective from 12:01 a.m. on Wednesday, July 6, 2016 through 12:01 a.m. on Monday, September 12, 2016.

(e) *Navigation Rules.* The Navigation Rules shall apply at all times within a tall ships safety zone.

Dated: July 5, 2016.

J.E. Ryan,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2016–16711 Filed 7–13–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2015–0810; FRL–9948–81]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for three chemical substances, which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if an adverse comment is received. EPA received adverse comments regarding the SNURs identified in this document. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

DATES: This rule is effective July 15, 2016.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2015–0810, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** of May 16, 2016 (81 FR 30452) (FRL–9944–77). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What direct final SNURs are being withdrawn?

In the May 16, 2016 **Federal Register**, EPA issued direct final SNURs for the chemical substances that are identified in this document. These direct final SNURs were issued under the procedures in 40 CFR part 721, subpart D. Because the Agency received notices of intent to submit adverse comments, in accordance with § 721.160(c)(3)(ii), EPA is withdrawing the direct final SNURS issued for the following chemical substances, which were the subject of PMNs: Functionalized carbon nanotubes (generic), (PMN P–15–276), Diisocyanato hexane, homopolymer, alkanoic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (generic), (PMN P–15–378), and Modified diphenylmethane diisocyanate prepolymer with polyol (generic), (PMN P–15–559). EPA intends to publish proposed SNURs for the chemical substances identified in this document.

For further information regarding EPA's direct final rulemaking procedures for issuing SNURs, see 40 CFR part 721, subpart D, and the **Federal Register** of July 27, 1989 (54 FR 31314).

III. Good Cause Finding

EPA determined that this document is not subject to the 30-day delay of effective date generally required by the Administrative Procedure Act (APA) (5 U.S.C. 553(d)) because of the time limitations for publication in the **Federal Register**. This document must publish on or before the effective date of the direct final rule containing the direct final SNURs being withdrawn.

IV. Statutory and Executive Order Reviews

This action withdraws regulatory requirements that have not gone into effect and which contain no new or amended requirements. As such, the Agency has determined that this action will not have any adverse impacts, economic or otherwise. The statutory and Executive Order review requirements applicable to the direct final rule were discussed in the May 16, 2016 **Federal Register**. Those review requirements do not apply to this action because it is a withdrawal and does not contain any new or amended requirements.

V. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). Section 808 of the CRA allows the issuing agency to make a rule effective sooner than otherwise provided by CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary, or contrary to the public interest. As required by 5 U.S.C. 808(2), this determination is supported by a brief statement in Unit III.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 7, 2016.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

§ 9.1 [Amended]

■ 2. In the table in § 9.1, under the undesignated center heading "Significant New Uses of Chemical Substances," remove §§ 721.10902, 721.10913 and 721.10920.

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§ 721.10902 [Removed]

■ 4. Remove § 721.10902.

§ 721.10913 [Removed]

■ 5. Remove § 721.10913.

§ 721.10920 [Removed]

■ 6. Remove § 721.10920.

[FR Doc. 2016–16576 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2016–0290; FRL–9948–97–Region 10]

Approval and Promulgation of Implementation Plans; Washington: Spokane Second 10-Year Carbon Monoxide Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the limited maintenance plan submitted on May 11, 2016, by the Washington Department of Ecology (Ecology), in cooperation with the Spokane Regional Clean Air Agency (SRCAA) for the Spokane carbon monoxide (CO) maintenance area (Spokane area or area). The Spokane area includes the cities of Spokane, Spokane Valley, Millwood, and surrounding urban areas in Spokane County, Washington. This plan addresses the second 10-year maintenance period for the National Ambient Air Quality Standards (NAAQS) promulgated for CO, as revised in 1985. The Spokane area has had no exceedances of the CO NAAQS since 1997 and monitored CO levels in the area continue to decline steadily. The EPA is also approving an alternative CO monitoring strategy for the Spokane area which was submitted as part of the limited maintenance plan.

DATES: This final rule is effective August 15, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2016–0290. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.*, Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air and Waste, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Air Planning Unit, Office of Air and Waste (AWT–150), Environmental Protection Agency, Region 10, 1200 Sixth Ave., Suite 900, Seattle, WA 98101; telephone number: (206) 553–0256; email address: *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background Information
II. Final Action
III. Incorporation by Reference
IV. Statutory and Executive Orders Review

I. Background Information

On May 27, 2016, the EPA proposed to approve the limited maintenance plan submitted by the State of Washington for the Spokane CO area, including proposed approval of an alternative CO monitoring strategy and removal of an obsolete site-specific order and amendment for the former Kaiser Aluminum and Chemical Corporation's aluminum reduction plant (81 FR 33632). An explanation of the Clean Air Act requirements, a detailed analysis of the submittal, and the EPA's reasons for proposing approval were provided in the notice of proposed rulemaking, and will not be restated here. The public comment period for this proposed rule ended on June 27, 2016. The EPA received no comments on the proposal.

II. Final Action

The EPA is approving the limited maintenance plan submitted by the State of Washington for the Spokane CO area. We are approving the request to remove the associated order and amendment for the former Kaiser Aluminum and Chemical Corporation's aluminum reduction plant located in Mead, Washington from incorporation by reference in the Washington State Implementation Plan (SIP) because the facility has been shut down, dismantled, and the operating permit has been revoked. We are also approving the State's alternative CO monitoring strategy for the Spokane area. The EPA's approval of this limited maintenance plan satisfies the Clean Air Act (CAA) section 175A requirements for the second 10-year period in the Spokane CO area.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference as described in the amendments to 40 CFR part 52 set forth below. These materials have been approved by the EPA for inclusion in the State implementation plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Orders Review

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

This SIP revision is not approved to apply on any Indian reservation land in Washington or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). However, consistent with EPA policy, the EPA provided a consultation opportunity to the Spokane Tribe in a letter dated September 11, 2015. The EPA did not receive a request for consultation.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 12, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

---

[1] 62 FR 27968 (May 22, 1997).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 29, 2016.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart WW—Washington

■ 2. In § 52.2470:

■ a. Amend paragraph (d) by removing the entries for "Kaiser Order DE 01 AQIS–3285" (state effective date 10/24/01) and "Kaiser Order Amendment #1 DE 01 AQIS–3285" (state effective date 4/9/03) from the table.

■ b. Amend paragraph (e) by adding an entry at the end of Table 2—Attainment, Maintenance, and Other Plans for "Carbon Monoxide 2nd 10-Year Limited Maintenance Plan."

The addition reads as follows:

§ 52.2470 Identification of plan.

* * * * *

(e) * * *

TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
* * * * * * *				
Carbon Monoxide 2nd 10-Year Limited Maintenance Plan.	Spokane	5/11/16	7/14/2016, [Insert **Federal Register** citation]	

[FR Doc. 2016–16452 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2015–0839; FRL–9948–93–Region 4]

Determination of Attainment; Atlanta, Georgia; 2008 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to determine that the Atlanta, Georgia, 2008 Ozone National Ambient Air Quality Standard (NAAQS) Moderate Nonattainment Area ("Atlanta Area" or the "Area") has attained the 2008 8-hour ozone NAAQS. This final determination is based upon complete, quality-assured, and certified ambient air monitoring data showing that the Area has monitored attainment of the 2008 8-hour ozone NAAQS for the 2013–2015 monitoring period. The requirement for this Area to submit an attainment demonstration and associated reasonably available control measures (RACM), reasonable further progress (RFP) plans, contingency measures, and other planning state implementation plans (SIPs) related to attainment of the 2008 8-hour ozone NAAQS is suspended until EPA redesignates the Area to attainment, approves a redesignation substitute, or determines that the Area has violated the 2008 8-hour ozone NAAQS. This final attainment determination does not constitute a redesignation to attainment. The Atlanta Area will remain in nonattainment status for the 2008 8-hour ozone NAAQS until such time as the State requests a redesignation to attainment and EPA determines that the Atlanta Area meets the Clean Air Act (CAA or Act) requirements for redesignation, including an approved maintenance plan.

DATES: This rule will be effective August 15, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2015–0839. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Jane Spann, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Spann can be reached via phone at (404) 562–9029 or via electronic mail at *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 12, 2008, EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 parts per million (ppm) (annual fourth-highest daily maximum 8-hour average concentration, averaged over three years) to provide increased protection of public health and the environment. *See* 73 FR 16436 (March 27, 2008). The 2008 ozone NAAQS retains the same general form and averaging time as the 0.08 ppm NAAQS set in 1997, but is set at a more protective level.

Effective July 20, 2012, EPA designated any area that was violating the 2008 8-hour ozone NAAQS based on the three most recent years (2008–2010) of air monitoring data as a nonattainment area. *See* 77 FR 30088 (May 21, 2012). The Atlanta Area, consisting of Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale counties, was designated as a marginal ozone nonattainment area. *See* 40 CFR 81.311. Areas that were designated as marginal ozone nonattainment areas were required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2015, based on 2012–2014 monitoring data. The Atlanta Area did not attain the 2008 8-hour ozone NAAQS by July 20, 2015, and therefore on April 11, 2016, the EPA Administrator signed a final rule reclassifying the Atlanta Area from a marginal nonattainment area to a moderate nonattainment area for the 2008 8-hour ozone standard. *See* 81 FR 26697 (May 4, 2016). Moderate areas are required to attain the 2008 8-hour ozone NAAQS by no later than July 20, 2018, six years after the effective date of the initial nonattainment designations. *See* 40 CFR 51.1103. Air quality monitoring data from the 2013–2015 monitoring period show that the Atlanta Area is now attaining the 2008 8-hour ozone NAAQS.

Under the provisions of EPA's ozone implementation rule for the 2008 8-hour ozone NAAQS (40 CFR part 51, subpart AA), if EPA issues a determination that an area is attaining the relevant standard, also known as a Clean Data Determination, the area's obligations to submit an attainment demonstration and associated RACM, RFP, contingency measures, and other planning SIPs related to attainment of the 2008 8-hour ozone NAAQS are suspended until EPA: (i) Redesignates the area to attainment for the standard or approves a redesignation substitute, at which time those requirements no longer apply; or (ii) EPA determines that the area has violated the standard, at which time the area is again required to submit such plans. *See* 40 CFR 51.1118. While these requirements are suspended, EPA is not precluded from acting upon these elements at any time if submitted to EPA for review and approval.

An attainment determination is not equivalent to a redesignation under section 107(d)(3) of the CAA. The designation status of the Atlanta Area will remain nonattainment for the 2008 8-hour ozone NAAQS until such time as EPA determines that the Area meets the CAA requirements for redesignation to attainment, including an approved maintenance plan, and redesignates the Area. Additionally, the determination of attainment is separate from, and does not influence or otherwise affect, any future designation determination or requirements for the Atlanta Area based on any new or revised ozone NAAQS, and the determination of attainment remains in effect regardless of whether EPA designates this Area as a nonattainment area for purposes of any new or revised ozone NAAQS.

In a notice of proposed rulemaking (NPRM) published on May 3, 2016, EPA proposed to determine that the Atlanta Area has attained the 2008 8-hour ozone NAAQS. *See* 81 FR 26515 (May 3, 2016). No comments were received on the May 3, 2016, proposed rulemaking. The details of Georgia's submittal and the rationale for EPA's actions are further explained in the NPRM. *See* 81 FR 26515 (May 3, 2016).

II. Final Action

EPA is making the determination that the Atlanta Area has attained the 2008 8-hour ozone NAAQS. This final determination is based upon complete, quality assured, and certified ambient air monitoring data showing that the Atlanta Area has monitored attainment of the 2008 8-hour ozone NAAQS for the 2013–2015 monitoring period. The requirement for this Area to submit an attainment demonstration and associated RACM, a RFP plan, contingency measures, and other planning SIPs related to attainment of the 2008 8-hour ozone NAAQS are suspended until EPA redesignates the Area to attainment, approves a redesignation substitute, or determines that the Area has violated the standard.

III. Statutory and Executive Order Reviews

This action makes a determination of attainment based on air quality data and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000) and will not impose substantial direct costs on tribal governments or preempt tribal law because it merely makes a determination based on air quality data.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 12, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Nitrogen dioxide, Volatile organic compounds.

Dated: June 27, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart L—Georgia

■ 2. Section 52.582 is amended by adding paragraph (e) to read as follows:

§ 52.582 Control strategy: Ozone.

* * * * *

(e) *Determination of attaining data.* EPA has determined, as of July 14, 2016, that the Atlanta, Georgia nonattainment area has attaining data for the 2008 8-hour ozone NAAQS. This determination, in accordance with 40 CFR 51.1118, suspends the requirements for this area to submit attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures for failure to attain or make reasonable progress, and other planning SIPs related to attainment of the 2008 ozone NAAQS, or for any prior NAAQS for which the determination has been made, until such time as: The area is redesignated to attainment for that NAAQS or a redesignation substitute is approved as appropriate, at which time the requirements no longer apply; or EPA determines that the area has violated that NAAQS, at which time the area is again required to submit such plans.

[FR Doc. 2016–16449 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0106; FRL–9948–95–Region 4]

Air Plan Approval; NC; Fine Particulate Matter National Ambient Air Quality Standards Revision

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to a State Implementation Plan (SIP) submitted by the State of North Carolina, through the North Carolina Department of Environmental Quality's (NCDEQ) Division of Air Quality (DAQ) on December 11, 2015, that incorporates amendments to the state rules reflecting the 2012 national ambient air quality standards (NAAQS) for fine particulate matter ($PM_{2.5}$). This action is being taken pursuant to the Clean Air Act (CAA or Act).

DATES: This direct final rule is effective September 12, 2016 without further notice, unless EPA receives adverse comment by August 15, 2016. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0106 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Madolyn Sanchez, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Sanchez can be reached via telephone at (404) 562–9644 or via electronic mail at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 108 and 109 of the CAA govern the establishment, review, and revision, as appropriate, of the NAAQS to protect public health and welfare. The CAA requires periodic review of the air quality criteria—the science upon which the standards are based—and the standards themselves. EPA's regulatory provisions that govern the NAAQS are found at 40 CFR 50—*National Primary and Secondary Ambient Air Quality Standards*. In this rulemaking, EPA is taking direct final action to approve North Carolina's December 11, 2015, submission amending the State's regulations to incorporate the NAAQS for $PM_{2.5}$, which are found at 15A North Carolina Administrative Code (NCAC) 02D .0410. The SIP submittal amending North Carolina's rules to incorporate the NAAQS can be found in the docket for this rulemaking at *www.regulations.gov* and is summarized below.

II. Analysis of State's Submittal

On December 14, 2012, EPA promulgated a revised primary annual $PM_{2.5}$ NAAQS. *See* 78 FR 3086. In that action, EPA revised the primary annual $PM_{2.5}$ standard, strengthening it from 15.0 micrograms per cubic meter ($\mu g/m^3$) to 12.0 $\mu g/m^3$, and retained the existing 24-hour $PM_{2.5}$ standard at 35 $\mu g/m^3$. Accordingly, in the December 11, 2015, SIP submittal, North Carolina revised state rule 15A NCAC 02D .0410 *$PM_{2.5}$ Particulate Matter* to update the primary air quality standard for $PM_{2.5}$ to be consistent with the NAAQS that were promulgated by EPA in 2012. EPA has reviewed this change to North Carolina's rule for $PM_{2.5}$ and has made the determination that this change is consistent with federal regulations.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of North Carolina regulation 15A NCAC 02D .0410 *$PM_{2.5}$ Particulate Matter* effective September 1, 2015, which was revised to be consistent with the current NAAQS. Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the **Federal Register** in the next update to the SIP compilation.[1] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 Office (please contact the person identified in the "For Further Information Contact" section of this preamble for more information).

IV. Final Action

EPA is approving the aforementioned change to the North Carolina SIP because it is consistent with EPA's 2012 $PM_{2.5}$ standards. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 12, 2016September 12, 2016 without further notice unless the Agency receives adverse comments by August 15, 2016.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 12, 2016 and no further action will be taken on the proposed rule.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 12, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter.

Dated: June 30, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 Part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

■ 2. Section 52.1770(c) is amended under Table 1, at "Subchapter 2D—Air Pollution Control Requirements", "Section .0400 Ambient Air Quality Standards" by revising the entry for "Sect .0410" to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

---

[1] 62 FR 27968 (May 22, 1997).

TABLE 1—EPA APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/Subject	State effective date	EPA Approval date	Explanation
Subchapter 2D Air Pollution Control Requirements				
* * * * * * *				
Section .0400 Ambient Air Quality Standards				
* * * * * * *				
Sect .0410	$PM_{2.5}$ Particulate Matter	9/1/2015	7/14/16, [Insert citation of publication]	
* * * * * * *				

* * * * *

[FR Doc. 2016–16458 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150818742–6210–02]

RIN 0648–XE728

Fisheries of the Exclusive Economic Zone Off Alaska; Reapportionment of the 2016 Gulf of Alaska Pacific Halibut Prohibited Species Catch Limits for the Trawl Deep-Water and Shallow-Water Fishery Categories

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reapportionment.

SUMMARY: NMFS is reapportioning the seasonal apportionments of the 2016 Pacific halibut prohibited species catch (PSC) limits for the trawl deep-water and shallow-water species fishery categories in the Gulf of Alaska. This action is necessary to account for the actual halibut PSC use by the trawl deep-water and shallow-water species fishery categories from May 15, 2016, through June 30, 2016. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), July 11, 2016, through 2400 hours, A.l.t., December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Gulf of Alaska (GOA) exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The final 2016 and 2017 harvest specifications for groundfish in the GOA (81 FR 14740, March 18, 2016) apportions the 2016 Pacific halibut PSC limit for trawl gear in the GOA to two trawl fishery categories: A deep-water species fishery and a shallow-water species fishery. The halibut PSC limit for these two trawl fishery categories is further apportioned by season, including four seasonal apportionments to the shallow-water species fishery and three seasonal apportionments to the deep-water species fishery. The two fishery categories also are apportioned a combined, fifth seasonal halibut PSC limit. Unused seasonal apportionments are added to the next season apportionment during a fishing year.

Regulations at § 679.21(d)(4)(iii)(D) require NMFS to combine management of the available trawl halibut PSC limits in the second season (April 1 through July 1) deep-water and shallow-water species fishery categories for use in either fishery from May 15 through June 30 of each year. Furthermore, NMFS is required to reapportion the halibut PSC limit between the deep-water and shallow-water species fisheries after June 30 to account for actual halibut PSC use by each fishery category during May 15 through June 30. As of July 6, 2016, NMFS has determined that the trawl deep-water and shallow-water fisheries used 28 metric tons (mt) and 32 mt of halibut PSC, respectively, from May 15 through June 30. Accordingly, pursuant to § 679.21(d)(4)(iii)(D), the Regional Administrator is reapportioning the combined first and second seasonal apportionments (810 mt) of halibut PSC limit between the trawl deep-water and shallow-water fishery categories to account for the actual PSC use (792 mt) in each fishery. Therefore, Table 15 of the final 2016 and 2017 harvest specifications for groundfish in the GOA (81 FR 14740, March 18, 2016) is revised consistent with this adjustment.

TABLE 15—FINAL 2016 AND 2017 APPORTIONMENT OF PACIFIC HALIBUT PSC TRAWL LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES

[Values are in metric tons]

Season	Shallow-water	Deep-water[1]	Total
January 20–April 1	257	92	349
April 1–July 1	144	299	443
Subtotal of combined first and second season limit (January 20–July 1)	401	391	792
July 1–September 1	180	350	530
September 1–October 1	128	Any remainder	128
Subtotal January 20–October 1	709	741	1,450
October 1–December 31[2]			256

TABLE 15—FINAL 2016 AND 2017 APPORTIONMENT OF PACIFIC HALIBUT PSC TRAWL LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES—Continued

[Values are in metric tons]

Season	Shallow-water	Deep-water [1]	Total
Total			1,706

[1] Vessels participating in cooperatives in the Central GOA Rockfish Program will receive 191 mt of the third season (July 1 through September 1) deep-water species fishery halibut PSC apportionment.

[2] There is no apportionment between trawl shallow-water and deep-water species fishery categories during the fifth season (October 1 through December 31).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would allow for harvests that exceed the originally specified apportionment of the halibut PSC limits to the deep-water and shallow-water fishery categories. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 8, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 8, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16648 Filed 7–11–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 135
Thursday, July 14, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SATS No. IN–164–FOR; Docket ID: OSM–2016–0004; S1D1S SS08011000 SX064A000 167S180110 S2D2S SS08011000 SX064A000 16XS501520]

Indiana Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Indiana Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter, the Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Indiana proposes to revise its Plan to reflect the 2006 changes to SMCRA.

This document gives the times and locations that the Indiana Plan and this proposed amendment to that Plan are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., c.t., August 15, 2016. If requested, we will hold a public hearing on the amendment on August 8, 2016. We will accept requests to speak at a hearing until 4:00 p.m., c.t. on July 29, 2016.

ADDRESSES: You may submit comments, identified by SATS No. IN–164–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Len V. Meier, Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle St., Suite 216, Alton, IL 62002
- *Fax:* (618) 463–6470
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Indiana Plan, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Alton Field Division or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Len V. Meier, Chief
Alton Field Division
Office of Surface Mining Reclamation and Enforcement
501 Belle Street, Suite 216
Alton, Illinois 62002–6169
Telephone: (618) 463–6460
Email: lmeier@osmre.gov

In addition, you may review a copy of the amendment during regular business hours at the following location:

Indiana Department of Natural Resources
Division of Reclamation
14619 West State Road 48
Jasonville, IN 47438
Telephone: (812) 665–2207

FOR FURTHER INFORMATION CONTACT: Len V. Meier, Chief, Alton Field Division. Telephone: (618) 463–6460. Email: *lmeier@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Plan
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Indiana Plan

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act, (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a Plan) for the reclamation of abandoned coal mines. You can find background information on the Indiana Plan, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Indiana Plan in the April 26, 1999, **Federal Register** (64 FR 20166). You can also find later actions concerning the Indiana Plan and Plan amendments at 30 CFR 914.20 and 914.25.

II. Description of the Proposed Amendment

By letter dated March 14, 2016 (Administrative Record No. IN–1773), Indiana sent us an amendment to its AMLR Plan under SMCRA (30 U.S.C. 1201 *et seq.*). Indiana proposes to update the Indiana Plan as required by the 2006 Amendment to SMCRA. The full text of the Plan amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

We are seeking your comments on whether the amendment satisfies the applicable Plan approval criteria of 30 CFR 884.15. If we approve the amendment, it will become part of the State Plan.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.t. on July 29, 2016. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rulemaking is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a Plan amendment to OSMRE for review, our regulations at 30 CFR 884.14 and 884.15 require us to hold a public hearing on a Plan amendment if it changes the objectives, scope or major policies followed, or make a finding that the State provided adequate notice and opportunity for public comment. Indiana has elected to have OSMRE publish a notice in the **Federal Register** indicating receipt of the proposed amendment and soliciting comments. We will conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 10, 2016.

Sterling Rideout,

Acting Regional Director, Mid-Continent Region.

[FR Doc. 2016–16658 Filed 7–13–16; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

[SATS No. KS–029–FOR; Docket ID: OSM–2016–0003; S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Kansas Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Kansas Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter, the Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kansas proposes revisions to modernize its Plan, which remains largely unchanged since its approval on February 1, 1982, and encompasses the November 14, 2008, changes to the Federal regulations.

This document gives the times and locations that the Kansas Plan and proposed amendment to that Plan are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., c.t., August 15, 2016. If requested, we will hold a public hearing on the amendment on August 8, 2016. We will accept requests to speak at a hearing until 4:00 p.m., c.t. on July 29, 2016.

ADDRESSES: You may submit comments, identified by SATS No. KS–029–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 1645 South 101st East Avenue, Suite 145, Tulsa, Oklahoma 74128–4629.
- *Fax:* (918) 581–6419.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Kansas Plan, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Tulsa Field Office or going to *www.regulations.gov.*

Director
Tulsa Field Office
Office of Surface Mining Reclamation and Enforcement
1645 South 101st East Avenue, Suite 145
Tulsa, Oklahoma 74128–4629

Telephone: (918) 581–6430

In addition, you may review a copy of the amendment during regular business hours at the following location:

Kansas Department of Health and Environment
Surface Mining Section
4033 Parkview Drive
Frontenac, Kansas 66763
Telephone: (316) 231–8540.

FOR FURTHER INFORMATION CONTACT: Director, Tulsa Field Office. Telephone: (918) 581–6430. Email: *William L. Joseph* at *bjoseph@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Kansas Plan
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Kansas Plan

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act, (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a Plan) for the reclamation of abandoned coal mines. On February 1, 1982, the Secretary of the Interior approved the Kansas Plan. You can find background information on the Kansas Plan, including the Secretary's findings, the disposition of comments, and the approval of the Plan in the February 1, 1982, **Federal Register** (47 FR 4513). You can find later actions concerning the Kansas AMLR Plan and amendments to the Plan at 30 CFR 916.20 and 916.25.

II. Description of the Proposed Amendment

By letter dated February 23, 2016 (Administrative Record No. KS–628), Kansas sent us an amendment to its AMLR Plan under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative. Below is a summary of the changes proposed by Kansas. The full text of the Plan amendment is available for you to read at the locations listed above under **ADDRESSES**.

Kansas proposes to revise its Plan by modernizing it and encompassing the November 14, 2008, changes to the Federal regulations. The revised Plan addresses all the Federal requirements found in 30 CFR 884.13 regarding content of proposed State reclamation plans.

III. Public Comment Procedures

We are seeking your comments on whether the amendment satisfies the applicable Plan approval criteria of 30 CFR 884.15. If we approve the amendment, it will become part of the State Plan.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.t. on July 29, 2016. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rulemaking is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a Plan amendment to OSMRE for review, our regulations at 30 CFR 884.14 and 884.15 require us to hold a public hearing on a Plan amendment if it changes the objectives, scope or major policies followed, or make a finding that the State provided adequate notice and opportunity for public comment. Kansas has elected to have OSMRE publish a notice in the **Federal Register** indicating receipt of the proposed amendment and soliciting comments. We will conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 916

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 10, 2016.

Sterling Rideout, Acting Regional Director,
Mid-Continent Region.

[FR Doc. 2016–16657 Filed 7–13–16; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG–2014–0142]

RIN 1625–AA01

Anchorage Regulations; Special Anchorage Areas, Marina del Rey Harbor, California

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking; reopen comment period.

SUMMARY: The Coast Guard is re-opening the comment period for its supplemental notice of proposed rulemaking (SNPRM), published in May 2014. The Coast Guard is proposing to amend the shape and reduce the size of the special anchorage in Marina del Rey Harbor, California. Additionally, we propose to clarify the language in the note section of the existing regulation. Because the date of the public meeting was not published in the **Federal Register** until after the meeting was held, the Coast Guard is providing an additional opportunity for public comment.

DATES: Comments and related material must reach the Coast Guard on or before August 15, 2016.

ADDRESSES: You may submit written comments identified by docket number USCG–2014–0142 using the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the proposed rule, please call or email Lieutenant Junior Grade Colleen Patton, Waterways Management Branch, Eleventh Coast Guard District, telephone 510–437–5984, email *Colleen.M.Patton@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

We published a notice of proposed rulemaking (NPRM) in the **Federal Register** on May 28, 2014 (79 FR 30509), entitled "Anchorage Regulations: Special Anchorage Areas, Marina del Rey Harbor, California." The NPRM proposed to disestablish the special anchorage area. In response to comments received, we have issued a supplemental NPRM (81 FR 10156, February 29, 2016) to retain the special anchorage, but amend the shape and reduce the size of the anchorage to remove the anchorage area from a location where it could endanger vessel traffic.

Because the date of the public meeting was not published in the **Federal Register** until after the meeting was held, we have concluded that additional comments would aid this rulemaking. Therefore, we are publishing this document to reopen the comment period.

You may view the SNPRM, in our online docket, in addition to supporting documents prepared by the Coast Guard and comments submitted thus far by going to *http://www.regulations.gov.* Once there, insert "USCG–2014–0142" in the "Keyword" box and click "Search."

We encourage you to participate in this rulemaking by submitting comments to the docket through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Public Meeting

We do not now plan to hold another public meeting, but will consider holding one in response to a request from the public. You may submit a request for a meeting either by submitting a comment to the docket or by writing to Eleventh Coast Guard District at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that a meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice.

Reopening the Comment Period

The comment period for the SNPRM published in February 2016 ended April 30, 2016. In order to give the public a chance to make additional comments, the Coast Guard is reopening the comment period on our SNPRM. All comments must reach the public docket at the address found in **ADDRESSES** on or before August 15, 2016.

Dated: June 10, 2016.

J.A. Servidio,
RADM, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 2016–16713 Filed 7–13–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2014–0431; FRL–9948–98–Region 4]

Air Plan Approval/Disapproval; Alabama; Infrastructure Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve in part and disapprove in part portions of the April 23, 2013, State Implementation Plan (SIP) submission, submitted by the State of Alabama, through the Alabama Department of Environmental Management (ADEM), for inclusion into the Alabama SIP. This proposal pertains to the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2010 1-hour sulfur dioxide (SO_2) national ambient air quality standard (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP. ADEM certified that the Alabama SIP contains provisions that ensure the 2010 1-hour SO_2 NAAQS is implemented, enforced, and maintained in Alabama. With the exception of provisions respecting state boards, which EPA is proposing to disapprove, and interstate transport, which EPA is not proposing any action at this time, EPA is proposing to determine that portions of Alabama's infrastructure SIP submission provided to EPA on April 23, 2013, satisfy the required infrastructure elements for the 2010 1-hour SO_2 NAAQS.

DATES: Written comments must be received on or before August 15, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2014–0431 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Michele Notarianni, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Notarianni can be reached via electronic mail at *notarianni.michele@epa.gov* or via telephone at (404) 562–9031.

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On June 22, 2010 (75 FR 35520), EPA revised the primary SO_2 NAAQS to an hourly standard of 75 parts per billion (ppb) based on a 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2010 1-hour SO_2 NAAQS to EPA no later than June 2, 2013.[1]

This action is proposing to approve Alabama's infrastructure SIP submission for the applicable requirements of the 2010 1-hour SO_2 NAAQS, with the exception of interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states and visibility protection requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4) and the state board requirements of section 110(a)(2)(E)(ii). With respect to the interstate transport provisions of section 110(a)(2)(D)(i)(I) (prongs 1 and 2) and the visibility protection requirements of section 110(a)(2)(D)(i)(II) (prong 4), EPA is not proposing any action at this time regarding these requirements. With respect to Alabama's infrastructure SIP submission related to section 110(a)(2)(E)(ii) requirements respecting the section 128 state board requirements, EPA is proposing to disapprove this element of Alabama's submission in this rulemaking. For the aspects of Alabama's submittal proposed for approval today, EPA notes that the Agency is not approving any specific rule, but rather proposing that Alabama's already approved SIP meets certain CAA requirements.

II. What elements are required under Sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for "infrastructure" SIP requirements related to a newly established or revised NAAQS. As mentioned previously, these requirements include basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. The requirements of section 110(a)(2) are summarized later on and in EPA's September 13, 2013, memorandum entitled "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)."[2]

- 110(a)(2)(A): Emission Limits and Other Control Measures
- 110(a)(2)(B): Ambient Air Quality Monitoring/Data System
- 110(a)2(C): Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources[3]
- 110(a)(2)(D)(i)(I) and (II): Interstate Pollution Transport
- 110(a)(2)(D)(ii): Interstate Pollution Abatement and International Air Pollution
- 110(a)(2)(E): Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies
- 110(a)(2)(F): Stationary Source Monitoring and Reporting
- 110(a)(2)(G): Emergency Powers
- 110(a)(2)(H): SIP Revisions
- 110(a)(2)(I): Plan Revisions for Nonattainment Areas[4]
- 110(a)(2)(J): Consultation with Government Officials, Public Notification, and Prevention of Significant Deterioration (PSD) and Visibility Protection
- 110(a)(2)(K): Air Quality Modeling and Submission of Modeling Data
- 110(a)(2)(L): Permitting fees
- 110(a)(2)(M): Consultation and Participation by Affected Local Entities

---

[1] In these infrastructure SIP submissions States generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federally-approved SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Throughout this rulemaking, unless otherwise indicated, the term "ADEM Administrative Code (Admin. Code r)." indicates that the cited regulation has either been approved, or submitted for approval into Alabama's federally-approved SIP. The term "Alabama Code" (Ala. Code) indicates cited Alabama state statutes, which are not a part of the SIP unless otherwise indicated.

[2] Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D, title I of the CAA; and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, title I of the CAA. This proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

[3] This rulemaking only addresses requirements for this element as they relate to attainment areas.

[4] As mentioned previously, this element is not relevant to this proposed rulemaking.

III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Alabama that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2010 1-hour SO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[5] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that "each" SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.[6] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.[7] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit "a plan" to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[8] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[9]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure

---

[5] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

[6] *See, e.g.,* "Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule," 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[7] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.,* that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

[8] *See, e.g.,* "Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting," 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and "Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS," (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[9] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[10]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the "applicable requirements" of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[11] EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).[12] EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[13] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's implementation plan appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.*, whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and new source review (NSR) pollutants, including greenhouse gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 fine particulate matter ($PM_{2.5}$) NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's implementation plan meets basic structural requirements. For example, section 110(a)(2)(C) includes, among other things, the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor NSR program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.*, already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

---

[10] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[11] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[12] "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013.

[13] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the United States (U.S.) Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City*, 696 F.3d7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions ("SSM"); (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final NSR Improvement Rule," 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) ("NSR Reform"). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[14] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's implementation plan is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[15] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[16] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[17]

IV. What is EPA's analysis of how Alabama addressed the elements of the Sections 110(a)(1) and (2) "Infrastructure" provisions?

Alabama's infrastructure SIP submission addresses the provisions of sections 110(a)(1) and (2) as described later on.

1. 110(a)(2)(A): *Emission Limits and Other Control Measures:* Section 110(a)(2)(A) requires that each implementation plan include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements. Several regulations within Alabama's SIP are relevant to air quality control regulations. The regulations described later on have been federally approved in the Alabama SIP and include enforceable emission limitations and other control measures. ADEM Admin. Code r. 335–3–1–.03—*Ambient Air Quality Standards,* authorizes ADEM to adopt rules for the control of air pollution in order to comply with NAAQS, including those necessary to obtain EPA approval under section 110 of the CAA. ADEM Admin. Code r. 335–3–1–.06—*Compliance Schedule,* sets the schedule for compliance with the State's Air Pollution Control rules and

---

[14] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

[15] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 74 FR 21639 (April 18, 2011).

[16] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[17] *See, e.g.,* EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). *See, e.g.,* 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

regulations to be consistent with the requirements of the CAA. ADEM Admin. Code r. 335–3–1–05—*Sampling and Testing Methods,* details the authority and means with which ADEM can require testing and emissions verification. Also, the following ADEM Administrative Code rules regulate stack height: 335–3–14–03(2)—*Stack Heights, subparagraphs (d) and (e), 335–3–15–02(9)—Stack Heights, subparagraphs (d) and (e), and 335–3–16–.02(10)—General Provisions, subparagraphs (d) and (e).* EPA has made the preliminary determination that Alabama's SIP satisfies Section 110(a)(2)(A) for the 2010 1-hour SO_2 NAAQS in the State.

In this action, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown" (September 20, 1999), and the Agency is addressing such state regulations in a separate action.[18]

Additionally, in this action, EPA is not proposing to approve or disapprove any existing State rules with regard to director's discretion or variance provisions. EPA believes that a number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109 (November 24, 1987)), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B) *Ambient Air Quality Monitoring/Data System:* Section 110(a)(2)(B) requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to (i) monitor, compile, and analyze data on ambient air quality, and (ii) upon request, make such data available to the Administrator. ADEM Admin. Code r. 335–3–1–.04—*Monitoring, Records, and Reporting,* requires sources to submit emissions monitoring reports as prescribed by the Director of ADEM. Pursuant to this regulation, these sources collect air monitoring data, quality assure the results, and report the data to EPA. ADEM Admin. Code r. 335–3–1–.05—*Sampling and Testing Methods,* details the authority and means through which ADEM can require testing and emissions verification. ADEM Admin. Code r. 335–3–14–.04—*Air Permits Authorizing Construction in Clean Air: Prevention of Significant Deterioration Permitting (PSD),* describes the State's use of ambient air quality monitoring data for purposes of permitting new facilities and assessing major modifications to existing facilities. Annually, States develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, and includes the annual ambient monitoring network design plan and a certified evaluation of the agency's ambient monitors and auxiliary support equipment.[19] On July 22, 2015, Alabama submitted its plan to EPA. On November 19, 2015, EPA approved Alabama's monitoring network plan. Alabama's approved monitoring network plan can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2014–0431. EPA has made the preliminary determination that Alabama's SIP and practices are adequate for the ambient air quality monitoring and data system related to the 2010 1-hour SO_2 NAAQS.

3. 110(a)(2)(C) *Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources:* This element consists of three sub-elements: Enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources, and preconstruction permitting of major sources and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (*i.e.,* the major source PSD program). ADEM's 2010 1-hour SO_2 NAAQS infrastructure SIP submission cited a number of SIP provisions to address these requirements. Specifically, the submission cited ADEM Admin. Code r. 335–3–14–.01—*General Provisions,* 335–3–14–.02,—*Permit Procedure,* 335–3–14–.03—*Standards for Granting Permits,* 335–3–14–.04—*Prevention of Significant Deterioration in Permitting* and 335–3–14–.05—*Air Permits Authorizing Construction in or Near Nonattainment Areas.* Collectively, these provisions of Alabama's SIP regulate the construction of any new major stationary source or any modification at an existing major stationary source in an area designated as nonattainment, attainment or unclassifiable.

Enforcement: ADEM's above-described, SIP-approved regulations provide for enforcement of SO_2 emission limits and control measures through construction permitting for new or modified stationary sources. Note also that ADEM has authority to issue enforcement orders and assess penalties (*see* Ala. Code sections 22–22A–5, 22–28–10 and 22–28–22).

PSD Permitting for Major Sources: EPA interprets the PSD sub-element to require that a state's infrastructure SIP submission for a particular NAAQS demonstrate that the state has a complete PSD permitting program in place covering the structural PSD requirements for all regulated NSR pollutants. A state's PSD permitting program is complete for this sub-element (and prong 3 of D(i) and J related to PSD) if EPA has already approved or is simultaneously approving the state's implementation plan with respect to all structural PSD requirements that are due under the EPA regulations or the CAA on or before the date of the EPA's proposed action on the infrastructure SIP submission.

For the 2010 1-hour SO_2 NAAQS, Alabama's authority to regulate new and modified sources to assist in the protection of air quality in Alabama is established in the Alabama Administrative Code Chapters 335–3–14–.01—*General Provisions,* 335–3–14–.02—*Permit Procedure,* 335–3–14–.03—*Standards for Granting Permits,* 335–3–14–.04—*Prevention of Significant Deterioration in Permitting,* and 335–3–14–.05—*Air Permits Authorizing Construction in or Near Nonattainment Areas.* Alabama's SIP contains the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD elements.[20]

As such, EPA has made the preliminary determination that Alabama's SIP satisfies this PSD element for the 2010 1-hour SO_2 NAAQS.

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the SIP to include provisions that govern the minor source program that regulates emissions of the 2010 1-hour SO_2 NAAQS. ADEM Admin. Code r. 335–3–14–.01 *General Provisions,* 335–3–14–.02 *Permit Procedure,* and 335–3–14–.03—*Standards for Granting Permits* govern the preconstruction permitting of modifications and construction of minor stationary sources.

---

[18] On June 12, 2015, EPA published a final action entitled, "State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction." *See* 80 FR 33840.

[19] On occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

[20] For more information on EPA's analysis of Alabama's infrastructure SIP in connection with the current PSD-related infrastructure requirements, see the Technical Support Document in the docket for this rulemaking.

EPA has made the preliminary determination that Alabama's SIP and practices are adequate for program enforcement of control measures and regulation of minor sources and modifications, and preconstruction permitting of modifications and construction of minor stationary sources, and minor modifications of major stationary sources related to the 2010 1-hour SO_2 NAAQS.

4. 110(a)(2)(D)(i)(I) and (II) *Interstate Pollution Transport:* Section 110(a)(2)(D)(i) has two components: 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components has two subparts resulting in four distinct components, commonly referred to as "prongs," that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state ("prong 1"), and interfering with maintenance of the NAAQS in another state ("prong 2"). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state ("prong 3"), or to protect visibility in another state ("prong 4").

110(a)(2)(D)(i)(I)—prongs 1 and 2: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states of section 110(a)(2)(D)(i)(I) (prongs 1 and 2) because Alabama's 2010 1-hour SO_2 NAAQS infrastructure submission did not address prongs 1 and 2.

110(a)(2)(D)(i)(II)—prong 3: With regard to section 110(a)(2)(D)(i)(II), the PSD element, referred to as prong 3, this requirement may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to: A PSD program meeting current structural requirements of part C of title I of the CAA, or (if the state contains a nonattainment area that has the potential to impact PSD in another state) a NNSR program. As discussed in more detail previously under section 110(a)(2)(C), Alabama's SIP contains provisions for the State's PSD program that reflect the required structural PSD requirements to satisfy the requirement of prong 3. EPA has made the preliminary determination that Alabama's SIP satisfies section 110(a)(2)(D)(i)(II) (prong 3) for PSD permitting of major sources and major modifications related to interstate transport for the 2010 1-hour SO_2 NAAQS.

110(a)(2)(D)(i)(II)—prong 4: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states of section 110(a)(2)(D)(i)(II) (prong 4) and will consider these requirements in relation to Alabama's 2010 1-hour SO_2 NAAQS infrastructure submission in a separate rulemaking.

5. 110(a)(2)(D)(ii) *Interstate and International Transport Provisions:* Section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement. ADEM Admin. Code r. 335–3–14–.04—*Prevention of Significant Deterioration in Permitting* describes how Alabama notifies neighboring states of potential emission impacts from new or modified sources applying for PSD permits. This regulation requires ADEM to provide an opportunity for a public hearing to the public, which includes state or local air pollution control agencies, "whose lands may be affected by emissions from the source or modification" in Alabama. Additionally, Alabama does not have any pending obligation under sections 115 and 126 of the CAA. EPA has made the preliminary determination that Alabama's SIP and practices are adequate for ensuring compliance with the applicable requirements relating to interstate and international pollution abatement for the 2010 1-hour SO_2 NAAQS.

6. 110(a)(2)(E) *Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies:* Section 110(a)(2)(E) requires that each implementation plan provide: (i) Necessary assurances that the state will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the state comply with the requirements respecting state boards pursuant to section 128 of the Act, and (iii) necessary assurances that, where the state has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the state has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Alabama's infrastructure SIP submission as meeting the requirements of sub-elements 110(a)(2)(E)(i) and (iii). With respect to sub-element 110(a)(2)(E)(ii) (regarding state boards), EPA is proposing to disapprove this sub-element. EPA's rationale respecting each sub-element is described in turn later on.

In support of EPA's proposal to approve sub-elements 110(a)(2)(E)(i) and (iii), ADEM's infrastructure submission demonstrates that it is responsible for promulgating rules and regulations for the NAAQS, emissions standards, general policies, a system of permits, fee schedules for the review of plans, and other planning needs as authorized at Ala. Code section 22–28–11 and section 22–28–9. As evidence of the adequacy of ADEM's resources with respect to sub-elements (i) and (iii), EPA submitted a letter to Alabama on April 19, 2016, outlining 105 grant commitments and current status of these commitments for fiscal year 2015. The letter EPA submitted to Alabama can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2014–0431. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. There were no outstanding issues in relation to the SIP for fiscal year 2015, therefore, Alabama's grants were finalized and closed out. Alabama's funding is also met through the state's title V fee program at ADEM Admin. Code r. 335–1–7—*Air Division Operating Permit Fees*[21] and ADEM Admin. Code r. 335–1–6—*Application Fees.*[22] In addition, the requirements of 110(a)(2)(E)(i) and (iii) are met when EPA performs a completeness determination for each SIP submittal. This determination ensures that each submittal provides evidence that adequate personnel, funding, and legal authority under state law has been used to carry out the state's implementation plan and related issues. Alabama's authority to implement provisions of the State's implementation plan is included in all prehearings and final SIP submittal packages for approval by EPA. EPA has made the preliminary determination that Alabama has adequate authority and resources for implementation of the 2010 1-hour SO_2 NAAQS.

---

[21] Title V program regulations are federally-approved but not incorporated into the federally-approved SIP.

[22] This regulation has not been incorporated into the federally-approved SIP.

Section 110(a)(2)(E)(ii) requires that SIPs comply with section 128 of the CAA. Section 128 requires that SIPs contain provisions to provide that: (1) The majority of members of the state board or body which approves permits or enforcement orders represent the public interest and do not derive any significant portion of their income from persons subject to permitting or enforcement orders under the CAA; and (2) any potential conflicts of interest by such board or body, or the head of an executive agency with similar powers be adequately disclosed. After reviewing Alabama's SIP, EPA has made the preliminary determination that the State's implementation plan does not contain provisions to comply with section 128 of the Act, and thus Alabama's April 23, 2013, infrastructure SIP submission does not meet the requirements of the Act. While Alabama has state statutes that may address, in whole or part, requirements related to state boards at the state level, these provisions are not included in the SIP as required by the CAA. Based on an evaluation of the federally-approved Alabama SIP, EPA is proposing to disapprove Alabama's certification that its SIP meets the requirements of 110(a)(2)(E)(ii) of the CAA for the 2010 1-hour SO_2 NAAQS. The submitted provisions which purport to address 110(a)(2)(E)(ii) are severable from the other portions of ADEM's infrastructure SIP submission, therefore, EPA is proposing to disapprove those provisions which relate only to sub-element 110(a)(2)(E)(ii).

7. 110(a)(2)(F) *Stationary Source Monitoring and Reporting:* Section 110(a)(2)(F) requires SIPs to meet applicable requirements addressing: (i) The installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources, (ii) periodic reports on the nature and amounts of emissions and emissions related data from such sources, and (iii) correlation of such reports by the state agency with any emission limitations or standards established pursuant to this section, which reports shall be available at reasonable times for public inspection. ADEM's infrastructure SIP submission describes the establishment of requirements for compliance testing by emissions sampling and analysis, and for emissions and operation monitoring to ensure the quality of data in the State. The Alabama infrastructure SIP submission also describes how the major source and minor source emission inventory programs collect emission data throughout the State and ensure the quality of such data. Alabama meets these requirements through ADEM Admin. Code r. 335–3–1–.04—*Monitoring, Records, and Reporting,* and 335–3–12—*Continuous Monitoring Requirements for Existing Sources.* ADEM Admin. Code r. 335–3–1–.04, details how sources are required as appropriate to establish and maintain records; make reports; install, use, and maintain such monitoring equipment or methods; and provide periodic emission reports as the regulation requires. Additionally, ADEM Admin. Code r. 335–3–12–.02 requires owners and operators of emissions sources to "install, calibrate, operate and maintain all monitoring equipment necessary for continuously monitoring the pollutants."[23] ADEM Admin. Code r. 335–3–1–.13—*Credible Evidence,* makes allowances for owners and/or operators to utilize "any credible evidence or information relevant" to demonstrate compliance with applicable requirements if the appropriate performance or compliance test had been performed, for the purpose of submitting compliance certification and can be used to establish whether or not an owner or operator has violated or is in violation of any rule or standard. Accordingly, EPA is unaware of any provision preventing the use of credible evidence in the Alabama SIP.

Additionally, Alabama is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and the precursors that form them—NO_X, SO_2, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Alabama made its latest update to the 2011 NEI on May 7, 2013. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html.* EPA has made the preliminary determination that Alabama's SIP and practices are adequate for the stationary source monitoring systems related to the 2010 1-hour SO_2 NAAQS.

8. 110(a)(2)(G) *Emergency Powers:* This section requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority. Ala. Code sections 22–28–22, 22–28–14 and 22–28–21 grant ADEM authority to adopt regulations for the purpose of protecting human health, welfare and the environment as required by section 303 of the CAA. ADEM Admin. Code r. 335–3–2,—*Air Pollution Emergency,* provides for the identification of air pollution emergency episodes, episode criteria, and emissions reduction plans. Alabama's compliance with section 303 of the CAA and adequate contingency plans to implement such authority is also met by Ala. Code section 22–28–21 *Air Pollution Emergencies.* Ala. Code Section 22–28–21 provides ADEM the authority to order the "person or persons responsible for the operation or operations of one or more air contaminants sources" causing "imminent danger to human health or safety in question to reduce or discontinue emissions immediately." The order triggers a hearing no later than 24-hours after issuance before the Environmental Management Commission which can affirm, modify or set aside the Director's order. Additionally, the Governor can, by proclamation, declare, as to all or any part of said area, that an air pollution emergency exists and exercise certain powers in whole or in part, by the issuance of an order or orders to protect the public health. Under Ala. Code sections 22–28–3(a) and 22–28–10(2), ADEM also has the authority to issue such orders as may be necessary to effectuate the purposes of the Alabama Pollution Control Act, which includes achieving and maintaining such levels of air quality as will protect human health and safety and, to the greatest

---

[23] ADEM Admin. Code r. 335–3–12–.02 establishes that data reporting requirements for sources required to conduct continuous monitoring in the state should comply with data reporting requirements set forth at 40 CFR part 51, Appendix P. Section 40 CFR part 51, Appendix P includes that the averaging period used for data reporting should be established by the state to correspond to the averaging period specified in the emission test method used to determine compliance with an emission standard for the pollutant/source category in question.

degree practicable, prevent injury to plant and animal life and property, foster the comfort and convenience of the people, promote the social development of this state and facilitate the enjoyment of the natural attractions of the state. EPA has made the preliminary determination that Alabama's SIP, state laws and practices are adequate to satisfy the infrastructure SIP obligations for emergency powers related to the 2010 1-hour SO_2 NAAQS. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(G).

9. 110(a)(2)(H) *SIP Revisions:* Section 110(a)(2)(H), in summary, requires each SIP to provide for revisions of such plan: (i) As may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and (ii) whenever the Administrator finds that the plan is substantially inadequate to attain the NAAQS or to otherwise comply with any additional applicable requirements. As previously discussed, ADEM is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS. Alabama has the ability and authority to respond to calls for SIP revisions, and has provided a number of SIP revisions over the years for implementation of the NAAQS. ADEM Admin. Code r. 335–1–1–.03—*Organization and Duties of the Commission,*[24] provides the Alabama Environmental Management Commission with the authority to establish, adopt, promulgate, modify, repeal and suspend rules, regulations, or environmental standards which may be applicable to Alabama or "any of its geographic parts." Admin. Code r. 335–3–1–.03—*Ambient Air Quality Standards,* incorporate NAAQS, as amended or revised, and provides that the NAAQS apply throughout the State. EPA has made the preliminary determination that Alabama adequately demonstrates a commitment to provide future SIP revisions related to the 2010 1-hour SO_2 NAAQS when necessary. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(H).

10. 110(a)(2)(J) *Consultation with government officials, public notification, and PSD and visibility protection:* EPA is proposing to approve Alabama's infrastructure SIP for the 2010 1-hour SO_2 NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that complies with the applicable consultation requirements of section 121, the public notification requirements of section 127, PSD and visibility protection. EPA's rationale for each sub-element is described later on.

Consultation with government officials (121 consultation): Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and Federal Land Managers (FLMs) carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. ADEM Admin. Code r. 335–3–1–.03—*Ambient Air Quality Standards,* as well as its Regional Haze Implementation Plan (which allows for continued consultation with appropriate state, local, and tribal air pollution control agencies as well as the corresponding FLMs), provide for consultation with government officials whose jurisdictions might be affected by SIP development activities. In addition, Alabama adopted state-wide consultation procedures for the implementation of transportation conformity which includes the development of mobile inventories for SIP development. These consultation procedures were developed in coordination with the transportation partners in the State and are consistent with the approaches used for development of mobile inventories for SIPs. Required partners covered by Alabama's consultation procedures include Federal, state and local transportation and air quality agency officials. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate consultation with government officials related to the 2010 1-hour SO_2 NAAQS when necessary.

Public notification (127 public notification): ADEM Admin. Code r. 335–3–14–.01(7)—*Public Participation,* and 335–3–14–.05(13)—*Public Participation,* and Ala. Code section 22–28–21—*Air Pollution Emergencies,* provide for public notification when air pollution episodes occur. Furthermore, ADEM has several public notice mechanisms in place to notify the public of ozone and $PM_{2.5}$ forecasting. Alabama maintains a public Web site on which daily air quality index forecasts are posted for the Birmingham, Huntsville, and Mobile areas. This Web site can be accessed at: *http://adem.alabama.gov/programs/air/airquality.cnt.* Although specific air quality forecasts for SO_2 are not provided, they are provided for $PM_{2.5}$ for which SO_2 is a precursor. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(J) public notification.

PSD: With regard to the PSD element of section 110(a)(2)(J), this requirement may be met by the state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a PSD program meeting current structural requirements of part C of title I of the CAA. As discussed in more detail previously under the section discussing 110(a)(2)(C), Alabama's SIP contains the required structural PSD requirements to satisfy the PSD element of section 110(a)(2)(J). Thus, EPA has made the preliminary determination that Alabama's SIP satisfies the PSD element of section 110(a)(2)(J) for the 2010 1-hour SO_2 NAAQS .

Visibility protection: EPA's 2013 Guidance notes that it does not treat the visibility protection aspects of section 110(a)(2)(J) as applicable for purposes of the infrastructure SIP approval process. ADEM referenced its regional haze program as germane to the visibility component of section 110(a)(2)(J). EPA recognizes that states are subject to visibility protection and regional haze program requirements under part C of the Act (which includes sections 169A and 169B). However, there are no newly applicable visibility protection obligations after the promulgation of a new or revised NAAQS. Thus, EPA has determined that states do not need to address the visibility component of 110(a)(2)(J) in infrastructure SIP submittals so ADEM does not need to rely on its regional haze program to fulfill its obligations under section 110(a)(2)(J). As such, EPA has made the preliminary determination that Alabama's submission is approvable for the visibility protection element of section 110(a)(2)(J) and that Alabama does not need to rely on its regional haze program to address this element.

11. 110(a)(2)(K) *Air Quality Modeling and Submission of Modeling Data:* Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and submission of such data to the EPA can be made. ADEM Admin. Code r. 335–3–14–.04—*Prevention of Significant Deterioration Permitting,* specifically sub-paragraph (11)—*Air Quality Models,* specifies that required air modeling be conducted in accordance with 40 CFR part 51, Appendix W "Guideline on Air Quality Models". ADEM Admin. Code r. 335–3–1–.04—*Monitoring, Records, and*

---

[24] This regulation has not been incorporated into the federally-approved SIP.

Reporting details how sources are required as appropriate to establish and maintain records; make reports; install, use, and maintain such monitoring equipment or methods; and provide periodic emission reports as the regulation requires. These reports and records are required to be compiled, and submitted on forms furnished by the State. These regulations also demonstrate that Alabama has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2010 1-hour SO_2 NAAQS. Additionally, Alabama participates in a regional effort to coordinate the development of emissions inventories and conduct regional modeling for several NAAQS, including the 2010 1-hour SO_2 NAAQS, for the southeastern states. Taken as a whole, Alabama's air quality regulations and practices demonstrate that ADEM has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of any emissions of any pollutant for which a NAAQS has been promulgated, and to provide such information to the EPA Administrator upon request. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate the State's ability to provide for air quality modeling, along with analysis of the associated data, related to the 2010–1-hour SO_2 NAAQS. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(K).

12. 110(a)(2)(L) *Permitting Fees:* This section requires the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover (i) the reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V. ADEM Admin. Code r. 335–1–6—*Application Fees*[25] requires ADEM to charge permit-specific fees to the applicant/source as authorized by Ala. Code section 22–22A–5. ADEM relies on these State requirements to demonstrate that its permitting fee structure is sufficient for the reasonable cost of reviewing and acting upon PSD and NNSR permits. Additionally, Alabama has a fully-approved title V operating permit program—ADEM Admin. Code r. 335–1–7—*Air Division Operating Permit Fees*[26]—that covers the cost of implementation and enforcement of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Alabama's state rules and practices adequately provide for permitting fees related to the 2010 1-hour SO_2 NAAQS, when necessary. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(L).

13. 110(a)(2)(M) *Consultation and Participation by Affected Local Entities:* Section 110(a)(2)(M) of the Act requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. ADEM coordinates with local governments affected by the SIP. ADEM Administrative Code 335–3–17–.01—*Transportation Conformity* is one way that Alabama provides for consultation with affected local entities. More specifically, Alabama adopted state-wide consultation procedures for the implementation of transportation conformity which includes the development of mobile inventories for SIP development and the requirements that link transportation planning and air quality planning in nonattainment and maintenance areas. Required partners covered by Alabama's consultation procedures include Federal, state and local transportation and air quality agency officials. Furthermore, ADEM has worked with the Federal Land Managers as a requirement of the regional haze rule. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate consultation with affected local entities related to the 2010 1-hour SO_2 NAAQS when necessary.

V. Proposed Action

With the exception of interstate transport provisions pertaining to visibility protection requirements of section 110(a)(2)(D)(i)(II) (prong 4), and the state board requirements of section 110(a)(2)(E)(ii), EPA is proposing to approve Alabama's April 23, 2013, SIP submission for the 2010 1-hour SO_2 NAAQS for the previously described infrastructure SIP requirements. EPA is proposing to disapprove section 110(a)(2)(E)(ii) of Alabama's infrastructure submission because the State's implementation plan does not contain provisions to comply with section 128 of the Act, and thus Alabama's April 23, 2013, infrastructure SIP submission does not meet the requirements of the Act. The interstate transport requirements of section 110(a)(2)(D)(i)(I) (prongs 1 and 2) will not be addressed by EPA at this time.

Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of a CAA Part D Plan, or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP call), starts a sanctions clock. The portion of section 110(a)(2)(E)(ii) provisions (the provisions being proposed for disapproval in this notice) were not submitted to meet requirements for Part D or a SIP call, and therefore, if EPA takes final action to disapprove this submittal, no sanctions will be triggered. However, if this disapproval action is finalized, that final action will trigger the requirement under section 110(c) that EPA promulgate a Federal Implementation Plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiency, and EPA approves the plan or plan revision before EPA promulgates such FIP.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

---

[25] This regulation has not been incorporated into the federally-approved SIP.

[26] Title V program regulations are federally approved but not incorporated into the federally-approved SIP.

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 30, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–16577 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2015–0252; FRL–9948–96–Region 4]

Air Plan Approval; Tennessee Infrastructure Requirements for the 2010 Nitrogen Dioxide National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of the State Implementation Plan (SIP) submission, submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), on March 13, 2014, to demonstrate that the State meets the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2010 nitrogen dioxide (NO_2) national ambient air quality standard (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP submission. TDEC certified that the Tennessee SIP contains provisions that ensure the 2010 NO_2 NAAQS is implemented, enforced, and maintained in Tennessee. With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting, and interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance, and visibility in other states, for which EPA is proposing no action through this rulemaking, EPA is proposing to find that Tennessee's infrastructure SIP submission, provided to EPA on March 13, 2014, satisfies the required infrastructure elements for the 2010 NO_2 NAAQS.

DATES: Written comments must be received on or before August 15, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2015–0252 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Wong can be reached via electronic mail at *wong.richard@epa.gov or via telephone at (404) 562–8726.*

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On February 9, 2010 (75 FR 6474), EPA published a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. *See* 75 FR 6474. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2010 1-hour NO_2 NAAQS to EPA no later than January 22, 2013.[1]

This action is proposing to approve Tennessee's infrastructure SIP submission for the applicable requirements of the 2010 1-hour NO_2 NAAQS, with the exception of the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J), and the interstate transport provisions of prongs 1, 2, and 4 of section 110(a)(2)(D)(i). On March 18, 2015, EPA approved Tennessee's March 13, 2014 infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) for the 2010 1-hour NO_2

---

[1] In these infrastructure SIP submissions States generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federally-approved SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Throughout this rulemaking, unless otherwise indicated, the term "Tennessee Air Pollution Control Regulations" or "Regulation" indicates that the cited regulation has been approved into Tennessee's federally-approved SIP. The term "Tennessee Annotated Code", or "TCA", indicates cited Tennessee state statutes, which are not a part of the SIP unless otherwise indicated.

NAAQS. *See* 80 FR 14019. Therefore, EPA is not proposing any action pertaining to these requirements. With respect to Tennessee's infrastructure SIP submission related to the interstate transport provisions of prongs 1, 2 and 4 of section 110(a)(2)(D)(i), EPA is not proposing any action today. EPA will act on these provisions in a separate action. For the aspects of Tennessee's submittal proposed for approval today, EPA notes that the Agency is not approving any specific rule, but rather proposing that Tennessee's already approved SIP meets certain CAA requirements.

II. What elements are required under Sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2010 1-hour NO_2 NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with previous NAAQS.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for "infrastructure" SIP requirements related to a newly established or revised NAAQS. As mentioned previously, these requirements include SIP infrastructure elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAQS. The requirements that are the subject of this proposed rulemaking are listed below and in EPA's September 13, 2013, memorandum entitled "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)."[2]

- 110(a)(2)(A): Emission Limits and Other Control Measures
- 110(a)(2)(B): Ambient Air Quality Monitoring/Data System
- 110(a)(2)(C): Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources[3]
- 110(a)(2)(D)(i)(I) and (II): Interstate Pollution Transport
- 110(a)(2)(D)(ii): Interstate Pollution Abatement and International Air Pollution
- 110(a)(2)(E): Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies
- 110(a)(2)(F): Stationary Source Monitoring and Reporting
- 110(a)(2)(G): Emergency Powers
- 110(a)(2)(H): SIP revisions
- 110(a)(2)(I): Plan Revisions for Nonattainment Areas[4]
- 110(a)(2)(J): Consultation with Government Officials, Public Notification, and PSD and Visibility Protection
- 110(a)(2)(K): Air Quality Modeling and Submission of Modeling Data
- 110(a)(2)(L): Permitting fees
- 110(a)(2)(M): Consultation and Participation by Affected Local Entities

III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Tennessee that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2010 NO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[5] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

---

[2] Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA; and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. This proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

[3] This rulemaking only addresses requirements for this element as they relate to attainment areas.

[4] As mentioned previously, this element is not relevant to this proposed rulemaking.

[5] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that "each" SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.[6] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.[7] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit "a plan" to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[8] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[9]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[10]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the "applicable requirements" of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[11] EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).[12] EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[13] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

---

[6] See, *e.g.*, "Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule," 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[7] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.*, that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

[8] See, *e.g.*, "Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting," 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and "Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS," (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[9] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

[10] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[11] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[12] "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's implementation plan appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.,* whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and NSR pollutants, including GHGs. By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 $PM_{2.5}$ NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's implementation plan meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia,* the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor new source review program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.,* already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions ("SSM"); (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final NSR Improvement Rule," 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) ("NSR Reform"). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[14] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility

---

Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013.

[13] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City,* 696 F.3d7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

[14] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's implementation plan is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[15] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[16] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[17]

IV. What is EPA's analysis of how Tennessee addressed the elements of the sections 110(a)(1) and (2) "infrastructure" provisions?

Tennessee's infrastructure submission addresses the provisions of sections 110(a)(1) and (2) as described below.

1. 110(a)(2)(A): *Emission limits and other control measures:* Section 110(a)(2)(A) requires that each implementation plan include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements. The Tennessee Code Annotated section 68–201–105(a) provides TDEC authority to establish limits and measures as well as schedules for compliance to meet the applicable requirements of the CAA. Emission limits and other control measures, means, and techniques as well as schedules and timetables for activities that contribute to NO_2 concentrations in the ambient air are found in Regulations 1200–03–03, *Ambient Air Quality Standards,* 1200–03–19, *Emission Standards and Monitoring Requirements for Additional Control Areas,* and 1200–03–27, *Nitrogen Oxides.* EPA has made the preliminary determination that the cited provisions adequately address 110(a)(2)(A) for the 2010 1-hour NO_2 NAAQS.

In this action, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown" (September 20, 1999), and the Agency is addressing such state regulations in a separate action.[18]

Additionally, in this action, EPA is not proposing to approve or disapprove any existing State rules with regard to director's discretion or variance provisions. EPA believes that a number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109 (November 24, 1987)), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B) *Ambient air quality monitoring/data system:* SIPs are required to provide for the establishment and operation of ambient air quality monitors, the compilation and analysis of ambient air quality data, and the submission of these data to EPA upon request. TCA 68–201–105(b)(4) provides TDEC with the authority to collect and disseminate information relating to air quality and pollution and the prevention, control, supervision, and abatement thereof. Annually, States develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, includes the annual ambient monitoring network design plan and a certified evaluation of the agency's ambient monitors and auxiliary support equipment.[19] On June 30, 2015, Tennessee submitted its monitoring network plan to EPA, and on October 26, 2015, EPA approved this plan. Tennessee's approved monitoring network plan can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2015–0252. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for the ambient air quality monitoring and data system related to the 2010 1-hour NO_2 NAAQS.

3. 110(a)(2)(C) *Program for Enforcement of Control Measures and for Construction or Modification of Stationary Sources:* This element consists of three sub-elements; enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and preconstruction permitting of major sources and major modifications in areas designated attainment or

---

[15] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 74 FR 21639 (April 18, 2011).

[16] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[17] See, *e.g.,* EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

[18] On June 12, 2015, EPA published a final action entitled, "State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction." *See* 80 FR 33840.

[19] On occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

unclassifiable for the subject NAAQS as required by CAA title I part C (*i.e.*, the major source PSD program). To satisfy the requirements of 110(a)(2)(C), Tennessee cites to Regulations 1200–03–09, *Construction and Operating Permits,* and 1200–03–13, *Violation.* These provisions of Tennessee's SIP pertain to the construction and modification of stationary sources and the enforcement of air pollution control regulations. As discussed further below, in this action EPA is only proposing to approve the enforcement, and the regulation of minor sources and minor modifications aspects of Tennessee's section 110(a)(2)(C) infrastructure SIP submission.

Enforcement: Regulation 1200–03–13, *Enforcement* provides for enforcement of emission limits and control measures and construction permitting for new or modified stationary sources. Also note, under TCA 68–201–116, *Orders and assessments of damages and civil penalty—Appeal,* the State's Technical Secretary is authorized to issue orders requiring correction of violations of any part of the Tennessee Air Quality Act, or of any regulation promulgated under this State statute. Violators are subject to civil penalties of up to $25,000 dollars per day for each day of violation and for any damages to the State resulting from the violations.

Preconstruction PSD Permitting for Major Sources: With respect to Tennessee's March 13, 2014, infrastructure SIP submission related to the PSD permitting requirements for major sources of section 110(a)(2)(C), EPA took final action to approve these provisions for the 2010 1-hour NO_2 NAAQS on March 18, 2015 (80 FR 14019).

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the SIP to include provisions that govern the minor source program that regulates emissions of the 2010 1-hour NO_2 NAAQS. Tennessee has a SIP-approved minor NSR permitting program at Regulations 1200–03–09–.01, *Construction Permits,* and 1200–03–09–.03, *General Provisions,* that regulates the preconstruction permitting of minor modifications and construction of minor stationary sources.

EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for program enforcement of control measures and regulation of minor sources and modifications related to the 2010 1-hour NO_2 NAAQS.

4. 110(a)(2)(D)(i) *Interstate Pollution Transport:* Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components have two subparts resulting in four distinct components, commonly referred to as "prongs," that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state ("prong 1"), and interfering with maintenance of the NAAQS in another state ("prong 2"). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state interfering with measures required to prevent significant deterioration of air quality in another state ("prong 3"), or to protect visibility in another state ("prong 4").

110(a)(2)(D)(i)(I)—prongs 1 and 2: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states of section 110(a)(2)(D)(i)(I) (prongs 1 and 2) because Tennessee's 2010 1-hour NO_2 NAAQS infrastructure submission did not address prongs 1 and 2.

110(a)(2)(D)(i)(II)—prong 3: With respect to Tennessee's infrastructure SIP submission related to the interstate transport requirements for PSD of section 110(a)(2)(D)(i)(II) (prong 3), EPA took final action to approve Tennessee's March 13, 2014, infrastructure SIP submission regarding prong 3 of D(i) for the 2010 1-hour NO_2 NAAQS on March 18, 2015. *See* 80 FR 14019.

110(a)(2)(D)(i)(II)—prong 4: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to visibility protection in other states of section 110(a)(2)(D)(i)(II) (prong 4) and will consider these requirements in relation to Tennessee's 2010 1-hour NO_2 NAAQS infrastructure submission in a separate rulemaking.

5. 110(a)(2)(D)(ii) *Interstate Pollution Abatement and International Air Pollution:* Section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement. Regulation 1200–03–09-.03,*General Provisions,* requires the permitting authority to notify air agencies whose areas may be affected by emissions from a source. EPA is unaware of any pending obligations for the State of Tennessee pursuant to sections 115 or 126 of the CAA. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for insuring compliance with the applicable requirements relating to interstate and international pollution abatement for the 2010 1-hour NO_2 NAAQS.

6. 110(a)(2)(E) *Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies:* Section 110(a)(2)(E) requires that each implementation plan provide (i) necessary assurances that the State will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the State comply with the requirements respecting State Boards pursuant to section 128 of the Act, and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Tennessee's SIP as meeting the requirements of sections 110(a)(2)(E). EPA's rationale for this proposals respecting each section of 110(a)(2)(E) is described in turn below.

In support of EPA's proposal to approve sub-elements 110(a)(2)(E)(i) and (iii), TCA 68–201–105, *Powers and duties of board—Notification of vacancy—Termination due to vacancy,* gives the Tennessee Air Pollution Control Board the power and duty to promulgate rules and regulations to implement the Tennessee Air Quality Act. The Board may define ambient air quality standards, set emission standards, set forth general policies or plans, establish a system of permits, and identify a schedule of fees for review of plans and specifications, issuance or renewal of permits or inspection of air contaminant sources.

TAPCR 1200–03–26, *Administrative Fees Schedule,* establishes construction fees, annual emission fees, and permit review fees sufficient to supplement existing State and Federal funding and to cover reasonable costs associated with the administration of Tennessee's air pollution control program. These costs include costs associated with the review of permit applications and reports, issuance of permits, source inspections and emission unit observations, review and evaluation of stack and/or ambient monitoring results, modeling, and costs associated with enforcement actions.

TCA 68–201–115, *Local pollution control programs—Exemption from state supervision—Applicability of part to air contaminant sources burning wood waste—Open burning of wood* *waste,* states that "Any municipality or county in this state may enact, by ordinance or resolution respectively, air pollution control regulations not less stringent than the standards adopted for the state pursuant to this part, or any such municipality or county may also adopt or repeal an ordinance or resolution which incorporates by reference any or all of the regulations of the board, or any federal regulations including any changes in such regulations, when such regulations are properly identified as to date and source." Before such ordinances or resolutions become effective, the municipality or county must receive a certificate of exemption from the Board to enact local regulations in the State. In granting any certificate of exemption, the State of Tennessee reserves the right to enforce any applicable resolution, ordinance, or regulation of the local program.

TCA 68–201–115 also directs TDEC to "frequently determine whether or not any exempted municipality or county meets the terms of the exemption granted and continues to comply with this section." If TDEC determines that the local program does not meet the terms of the exemption or does not otherwise comply with the law, the Board may suspend the exemption in whole or in part until the local program complies with the State standards.

As evidence of the adequacy of TDEC's resources, EPA submitted a letter to Tennessee on March 9, 2015, outlining section 105 grant commitments and the current status of these commitments for fiscal year 2014. The letter EPA submitted to Tennessee can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2015–0252. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Tennessee satisfactorily met all commitments agreed to in the Air Planning Agreement for fiscal year 2014, therefore Tennessee's grants were finalized. EPA has made the preliminary determination that Tennessee has adequate authority and resources for implementation of the 2010 1-hour NO_2 NAAQS.

Section 110(a)(2)(E)(ii) requires that the state to comply with section 128 of the CAA. Section 128 requires that the SIP provide: (a)(1) The majority of members of the state board or body which approves permits or enforcement orders represent the public interest and do not derive any significant portion of their income from persons subject to permitting or enforcement orders under the CAA; and (a)(2) any potential conflicts of interest by such board or body, or the head of an executive agency with similar powers be adequately disclosed. Section 110(a)(2)(E)(ii) obligations for the 2010 1-hour NO_2 NAAQS and the requirements of CAA section 128 are met in Regulation 0400–30–17, *Conflict of Interest.* Under this regulation, the Tennessee board with authority over air permits and enforcement orders is required to determine annually and after receiving a new member that at least a majority of its members represent to public interest and do not derive any significant portion of income from persons subject to such permits and enforcement orders. Further, the board cannot act to hear contested cases until it has determined it can do so consistent with CAA section 128. The regulation also requires TDEC's Technical Secretary and board members to declare any conflict-of-interest in writing prior to the issuance of any permit, variance or enforcement order that requires action on their part.

EPA has made the preliminary determination that the State has adequately addressed the requirements of section 128, and accordingly has met the requirements of section 110(a)(2)(E)(ii) with respect to infrastructure SIP requirements. Therefore, EPA is proposing to approve Tennessee's infrastructure SIP submission as meeting the requirements of sub-elements 110(a)(2)(E)(i), (ii) and (iii).

7. 110(a)(2)(F) *Stationary source monitoring system:* Section 110(a)(2)(F) requires SIPs to meet applicable requirements addressing (i) the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources, (ii) periodic reports on the nature and amounts of emissions and emissions related data from such sources, and (iii) correlation of such reports by the state agency with any emission limitations or standards established pursuant to this section, which reports shall be available at reasonable times for public inspection. Tennessee's infrastructure SIP submission describes how the State establishes requirements for emissions compliance testing and utilizes emissions sampling and analysis. It further describes how the State ensures the quality of its data through observing emissions and monitoring operations. These infrastructure SIP requirements are codified at Regulation 1200–03–10, *Required Sampling, Recording, and Reporting.* This rule requires owners or operators of stationary sources to compute emissions, submit periodic reports of such emissions and maintain records as specified by various regulations and permits, and to evaluate reports and records for consistency with the applicable emission limitation or standard on a continuing basis over time. The monitoring data collected and records of operations serve as the basis for a source to certify compliance, and can be used by Tennessee as direct evidence of an enforceable violation of the underlying emission limitation or standard. Accordingly, EPA is unaware of any provision preventing the use of credible evidence in the Tennessee SIP.

Additionally, Tennessee is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and the precursors that form them—nitrogen oxides, sulfur dioxide, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Tennessee made its latest update to the 2011 NEI on April 9, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html.* EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for the stationary source monitoring systems related to the 2010 1-hour NO_2 NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(F).

8. 110(a)(2)(G) *Emergency Powers:* Section 110(a)(2)(G) of the Act requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority. Tennessee's emergency powers are outlined in TAPCR 1200–03–15, *Emergency Episode Plan,* which establishes the criteria for declaring an air pollution

episode (air pollution alert, air pollution warning, or air pollution emergency), specific emissions reductions for each episode level, and emergency episode plan requirements for major sources located in or significantly impacting a nonattainment area. Additional emergency powers are codified in TCA 68–201–109, *Emergency Stop Orders for Air Contaminant Sources.* Under TCA 68–201–109, if the Commissioner of TDEC finds that emissions from the operation of one or more sources are causing imminent danger to human health and safety, the Commissioner may, with the approval of the Governor, order the source(s) responsible to reduce or discontinue immediately its (their) air emissions. Additionally, this State law requires a hearing to be held before the Commissioner within 24 hours of any such order.

Regarding the public welfare and environment, TCA 68–201–106, *Matters to be considered in exercising powers,* states that "In exercising powers to prevent, abate and control air pollution, the board or department shall give due consideration to all pertinent facts, including, but not necessarily limited to: (1) The character and degree of injury to, or interference with, the protection of the health, general welfare and physical property of the people . . ." Also, TCA 68–201–116, *Orders and assessments of damages and civil penalty Appeal,* provides in subsection (a) that if the Tennessee technical secretary discovers that any State air quality regulation has been violated, the Tennessee technical secretary may issue an order to correct the violation, and this order shall be complied with within the time limit specified in the order. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for emergency powers related to the 2010 1-hour NO_2 NAAQS2010 1-hour SO_2 NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(G).

9. 110(a)(2)(H) *Future SIP revisions:* Section 110(a)(2)(H), in summary, requires each SIP to provide for revisions of such plan (i) as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and (ii) whenever the Administrator finds that the plan is substantially inadequate to attain the NAAQS or to otherwise comply with any additional applicable requirements. As previously discussed, Tennessee is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS in Tennessee.

Section 68–201–105(a) of the Tennessee Air Quality Act authorizes the Tennessee Air Pollution Control Board to promulgate rules and regulations to implement this State statute, including setting and implementing ambient air quality standards, emission standards, general policies or plans, a permits system, and a schedule of fees for review of plans and specifications, issuance or renewal of permits, and inspection of sources. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate a commitment to provide future SIP revisions related to the 2010 1-hour NO_2 NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(H).

10. 110(a)(2)(J) *Consultation with Government Officials, Public Notification, and PSD and Visibility Protection:* EPA is proposing to approve Tennessee's infrastructure SIP submission for the 2010 1-hour NO_2 NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that provides for meeting the applicable consultation requirements of section 121, the public notification requirements of section 127; and visibility protection requirements of part C of the Act. With respect to Tennessee's infrastructure SIP submission related to the preconstruction PSD permitting requirements of section 110(a)(2)(J), EPA took final action to approve Tennessee's March 13, 2014, 2010 1-hour NO_2 NAAQS infrastructure SIP for these requirements on March 18, 2015. *See* 80 FR 14019. EPA's rationale for its proposed action regarding applicable consultation requirements of section 121, the public notification requirements of section 127, and visibility protection requirements is described below.

110(a)(2)(J) (121 consultation)—*Consultation with government officials:* Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and Federal Land Managers carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. Regulation 1200–03–34, *Conformity,* as well as Tennessee's Regional Haze Implementation Plan (which allows for consultation between appropriate state, local, and tribal air pollution control agencies as well as the corresponding Federal Land Managers), provide for consultation with government officials whose jurisdictions might be affected by SIP development activities. TAPCR 1200–03–34, *Conformity,* provides for interagency consultation on transportation and general conformity issues. Tennessee adopted state-wide consultation procedures for the implementation of transportation conformity which includes the development of mobile inventories for SIP development. Required partners covered by Tennessee's consultation procedures include Federal, state and local transportation and air quality agency officials. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate consultation with government officials related to the 2010 1-hour NO_2 NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(J) consultation with government officials.

110(a)(2)(J) (127 public notification)—*Public notification:* These requirements are met through Regulation 1200–03–15, *Emergency Episode Plan,* which requires that TDEC notify the public of any air pollution alert, warning, or emergency. The TDEC Web site also provides air quality summary data, air quality index reports and links to more information regarding public awareness of measures that can prevent such exceedances and of ways in which the public can participate in regulatory and other efforts to improve air quality. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate the State's ability to provide public notification related to the 2010 1-hour NO_2 NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submissions with respect to section 110(a)(2)(J) public notification.

110(a)(2)(J)—*Visibility protection:* EPA's 2013 Guidance notes that it does not treat the visibility protection aspects of section 110(a)(2)(J) as applicable for purposes of the infrastructure SIP approval process. EPA recognizes that states are subject to visibility protection and regional haze program requirements under Part C of the Act (which includes sections 169A and 169B). However, there are no newly applicable visibility protection obligations after the promulgation of a new or revised NAAQS. Thus, EPA has determined that states do not need to address the visibility component of 110(a)(2)(J) in infrastructure SIP submittals. As such, EPA has made the preliminary determination that it does not need to address the visibility protection element of section 110(a)(2)(J) in Tennessee's infrastructure SIP related to the 2010 1-hour NO_2 NAAQS.

11. 110(a)(2)(K) *Air Quality Modeling and Submission of Modeling Data:* Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and submission of such data to the EPA can be made. Regulation 1200–03-09-.01(4), *Prevention of Significant Air Quality Deterioration,* specifies that air modeling be conducted in accordance with 40 CFR part 51, Appendix W "Guideline on Air Quality Models." Tennessee also states that it has personnel with training and experience to conduct dispersion modeling consistent with models approved by EPA protocols. Also note that TCA 68–201–105(b)(7) grants TDEC the power and duty to collect and disseminate information relative to air pollution. Additionally, Tennessee supports a regional effort to coordinate the development of emissions inventories and conduct regional modeling for NOx, which includes NO_2. Taken as a whole, Tennessee's regulations, statutes and practices demonstrate that Tennessee has the authority to collect and provide relevant data for the purpose of predicting the effect on ambient air quality of the 1-hour NO_2 NAAQS. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate the State's ability to provide for air quality and modeling, along with analysis of the associated data, related to the 2010 1-hour NO_2 NAAQS when necessary.

12. 110(a)(2)(L) *Permitting fees:* This element necessitates that the SIP require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover (i) the reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

Funding for the Tennessee air permit program comes from a processing fee, submitted by permit applicants, required by Regulations 1200–03–26.02(5), *Construction Fee,* and 1200–03–26.02(9), *Annual Emissions Fees for Major Sources.* Tennessee ensures this is sufficient for the reasonable cost of reviewing and acting upon PSD and NNSR permits. Additionally, Tennessee has a fully approved title V operating permit program at Regulation 1200–03–09 [20] that covers the cost of implementation and enforcement of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Tennessee's SIP and practices adequately provide for permitting fees related to the 2010 NO_2 NAAQS, when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(L).

13. 110(a)(2)(M) *Consultation/participation by affected local entities:* Section 110(a)(2)(M) of the Act requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. TCA 68–201–105, *Powers and duties of board Notification of vacancy Termination due to vacancy,* authorizes and requires the Tennessee Air Pollution Control Board to promulgate rules and regulations related to consultation under the provisions of the State's Uniform Administrative Procedures Act. TCA 4–5–202, *When hearings required,* requires agencies to precede all rulemaking with a notice and public hearing, except for exemptions. TCA 4–5–203, *Notice of hearing,* states that whenever an agency is required by law to hold a public hearing as part of its rulemaking process, the agency shall: "(1) Transmit written notice of the hearings to the secretary of state for publication in the notice section of the administrative register Web site . . . and (2) Take such other steps as it deems necessary to convey effective notice to persons who are likely to have an interest in the proposed rulemaking." TCA 68–201–105(b)(7) authorizes and requires TDEC to "encourage voluntary cooperation of affected persons or groups in preserving and restoring a reasonable degree of air purity; advise, consult and cooperate with other agencies, persons or groups in matters pertaining to air pollution; and encourage authorized air pollution agencies of political subdivisions to handle air pollution problems within their respective jurisdictions to the greatest extent possible and to provide technical assistance to political subdivisions . . .". TAPCR 1200–03–34, *Conformity,* requires interagency consultation on transportation and general conformity issues. Additionally, TDEC has, in practice, consulted with local entities for the development of its transportation conformity SIP and has worked with the Federal Land Managers as a requirement of EPA's regional haze rule. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate consultation with affected local entities related to the 2010 1-hour NO_2 NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(M).

V. Proposed Action

With the exception of the preconstruction PSD permitting requirements for major sources of section 110(a)(2)(C), prong 3 of (D)(i), and (J) and the interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states and visibility of prongs 1, 2, and 4 of section 110(a)(2)(D)(i), EPA is proposing to approve that Tennessee's March 13, 2014, SIP submission for the 2010 1-hour NO_2 NAAQS has met the above-described infrastructure SIP requirements. EPA is proposing to approve Tennessee's infrastructure SIP submission for the 2010 1-hour SO_2 NAAQS because the submission is consistent with section 110 of the CAA.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities

---

[20] Title V program regulations are federally-approved but not incorporated into the federally-approved SIP.

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 30, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–16514 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0106; FRL–9948–94–Region 4]

Air Plan Approval; NC; Fine Particulate Matter National Ambient Air Quality Standards Revision

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of North Carolina, through the North Carolina Department of Environmental Quality's (NCDEQ) Division of Air Quality (DAQ) on December 11, 2015, that incorporates amendments to the state rules reflecting the 2012 national ambient air quality standards for fine particulate matter. EPA is approving this SIP revision because the State has demonstrated that it is consistent with the Clean Air Act.

DATES: Written comments must be received on or before August 15, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0106 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Madolyn Sanchez, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Sanchez can be reached via telephone at (404) 562–9644 or via electronic mail at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: June 30, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–16455 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 11–42, 09–197 and 10–90; Report No. 3046]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petitions for reconsideration and clarification.

SUMMARY: Petitions for Reconsideration and Clarification (Petitions) have been filed in the Commission's rulemaking proceeding by Thomas C. Power on behalf of CTIA, Kevin G. Rupy on behalf of United States Telecom Association, Colin W. Scott on behalf of Pennsylvania Public Utility Commission, John J. Heitmann on behalf of Joint Lifeline ETC Petitioners, John T. Nakahata on behalf of General Communication, Inc., Michael R. Romano on behalf of NTCA & WTA, Mitchell F. Brecher on behalf of TracFone Wireless, Inc., and David Springe on behalf of NASUCA.

DATES: Oppositions to the Petitions must be filed on or before July 29, 2016.

Replies to an opposition must be filed on or before August 8, 2016.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Christian Hoefly, Wireless Telecommunications Bureau, (202) 418–3607, email: *christian.hoefly@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 3046, released June 30, 2016. The full text of the Petitions is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554 or may be accessed online via the Commission's Electronic Comment Filing System at *http://apps.fcc.gov/ecfs/.* The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support, Connect America Fund, FCC 16–38, published at 81 FR 33026, May 24, 2016, in WC Docket Nos. 11–42, 09–197 and 10–90. This *Notice* is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 8.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–16619 Filed 7–13–16; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 81, No. 135
Thursday, July 14, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–LPS–16–0006]

U.S. Standards for Grades of Catfish and Catfish Products.

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice, request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) invites catfish producers, suppliers, processors, retailers, foodservice operators, and other interested stakeholders to provide background information, comments, and data to assist in the development of voluntary U.S. Standards for Grades of Catfish and Catfish Products. AMS is requesting comments concerning, but not limited to, the catfish quality standard that is currently implemented by the Department of Commerce (DOC), National Oceanic and Atmospheric Administration (NOAA), and National Marine Fisheries Service (NMFS).

DATES: Comments, information, and data relating to this notice are due no later than September 12, 2016.

ADDRESSES: Interested persons are invited to submit comments, information, and data relating to this notice by using the electronic process available at *http://www.regulations.gov,* or email: *catfishgrading@ams.usda.gov.* Written comments, information, and data may also be submitted to Catfish Grade Standards, Quality Assessment Division (QAD), 1400 Independence Avenue SW., Stop 0258, Room 3932–S, Washington, DC 20250 or by facsimile to (202) 690–2746.

FOR FURTHER INFORMATION CONTACT: David Bowden, Chief, Standardization Branch, QAD, Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Stop 0258, Room 3932–S, Washington, DC 20250, by phone (202) 690–3148, or via email: *David.Bowden@ams.usda.gov* or Bucky Gwartney, Marketing Specialist, Standardization Branch, QAD, Livestock, Poultry, and Seed Program at (202) 720–1424 or via email: *Bucky.Gwartney@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: The Agricultural Act of 2014 (2014 U.S. Farm Bill) directed the Secretary of Agriculture to establish, within USDA, a voluntary fee-based grading program for catfish. Section 203(c) of the Agricultural Marketing Act of 1946 (AMA) (7 U.S.C. 1621–1627) directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices." USDA is committed to carrying out this authority in a manner that facilitates the marketing of agricultural products. One method of achieving this objective is through the development and maintenance of voluntary standards by AMS. AMS Livestock, Poultry, and Seed Program's QAD Standardization Branch develops and maintains product and carcass standards for many different protein commodities. The development of grade standards for catfish and catfish products will assist the USDA in meeting its obligations under the 2014 U.S. Farm Bill.

Background

Since 1987, the NMFS has administered and applied the *U.S. Standards for Grades of North American Freshwater Catfish and Products Made Therefrom* (*http://www.seafood.nmfs.noaa.gov/pdfs/catfish.pdf*). While NMFS has a rigorous grading system, it may not be as recognizable to consumers as USDA graded products and is not utilized widely in the catfish industry. The longstanding USDA commodity grade standards are recognized, understood, valued, and expected by the consuming public.

AMS voluntary grade standards exist for many commodities, including a wide range of fruits, vegetables, poultry, meat, shell eggs, dairy, cotton, and other agricultural commodities. The application of these grade standards in their respective industries allows for the segregation and differentiation of product in accordance with quality attributes. Furthermore, creation of a grade standard often leads to broader opportunities to develop branded products through AMS certification, which serves to expand the market for the particular commodity and allow for the marketing of premium products.

The purpose of this Notice is to identify what the industry requires and needs in a catfish quality standard. We are seeking any recent research, industry data, and background information that will assist in the possible revision of or development of new catfish quality standards. Specific information is needed about catfish products, including both domestically produced and imported catfish, and how quality standards would promote value differentiation and create more objective market signals up and down the product and processing chain. Product standards also assist producers, processors, and retail segments in making informed management and marketing decisions. Additionally, any information regarding the use of quality specifications for value differentiation would be helpful.

To assist AMS in the potential development of catfish grade standards, background information, comments, and data are requested concerning the following:

1. Is there a need for AMS to develop a new voluntary catfish grade standards? If yes:

a. What key components should be included in the new voluntary standards for grades of catfish and catfish products?

b. What catfish and catfish product factors are currently being used by catfish producers, processors, and marketers to determine value?

c. Should voluntary grade standards for catfish include both quality and cutability (yield) determinations?

d. Are there currently any established industry catfish and catfish products standards being used by producers, processors, or marketers that could be useful in developing new AMS catfish and catfish products grade standards?

e. What are the consumer's expectations of catfish quality and how should a standard reflect those expectations?

f. How many tiers or levels of quality and/or yield should a catfish standard set forth?

g. Are there any additional species of farm-raised fish or farm-raised shellfish that AMS should take into consideration for a voluntary grading program?

AMS is soliciting comments from stakeholders about whether changes in the catfish quality grade standards should be made, and if so, what specific changes should be made. If after analyzing the comments, AMS determines that changes are warranted, a notice will be published in the **Federal Register** proposing specific changes. Interested parties will have an opportunity to comment prior to a final decision adopting any changes.

Therefore, we request your input regarding any catfish and catfish products background information, technical data, or research that you think will assist us on this matter.

Dated: June 11, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–16703 Filed 7–13–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0023]

Notice of Request for Approval of an Information Collection; National Animal Health Monitoring System; Antimicrobial Use Studies

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with the National Animal Health Monitoring System's studies on antimicrobial use in cattle feedlot and swine operations.

DATES: We will consider all comments that we receive on or before September 12, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0023.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0023* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Antimicrobial Use Studies, contact Mr. William Kelley, Supervisory Management and Program Analyst, Center for Epidemiology and Animal Health, VS, APHIS, 2150 Centre Avenue, Building B, MS 2E6, Fort Collins, CO 80526; (970) 494–7270. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Monitoring System; Antimicrobial Use Studies.

OMB Control Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to protect the health of U.S. livestock and poultry populations by preventing the introduction and interstate spread of serious diseases and pests of livestock and by eradicating such diseases from the United States when feasible. In connection with this mission, APHIS operates the National Animal Health Monitoring System (NAHMS), which collects data on the prevalence and economic importance of livestock diseases and associated risk factors.

NAHMS' national studies are a collaborative industry and government initiative to help determine the most effective means of preventing and controlling diseases of livestock. APHIS is the only agency responsible for collecting data on livestock health.

On March 20, 2012, NAHMS was recognized by the Office of Management and Budget (OMB) as a statistical unit under the Confidential Information Protection and Statistical Efficiency Act of 2002. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107–347, and other applicable Federal laws, all data provided to NAHMS under the antimicrobial use studies will be kept confidential and will not be disclosed in any identifiable form. Only NAHMS staff and designated agents will be permitted access to individual-level data. All information acquired under antimicrobial use studies will be used for statistical purposes only.

APHIS plans to initiate two annual antimicrobial use studies, one on cattle feedlots and one on swine operations. The studies' objectives are to describe antimicrobial use practices on livestock operations annually, including the impacts of U.S. Food and Drug Administration policy changes. The antimicrobial use studies will consist of Antimicrobial Use Producer Agreements and questionnaires administered by National Agricultural Statistics Service personnel. Information collected will be analyzed and organized by NAHMS into one or more descriptive reports containing summary statistics. The information will be used to describe current antimicrobial use practices; help policymakers and industry make informed decisions; assist researchers and private enterprise in identifying and focusing on vital issues related to antimicrobial use; facilitate education of future producers and veterinarians; and collect data capable of informing responses to objectives 2.4.3 and 2.4.4 of the National Action Plan for Combating Antibiotic-Resistant Bacteria.

We are asking OMB to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.4276 hours per response.

Respondents: Cattle feedlot personnel and swine owners and operators.

Estimated annual number of respondents: 7,200.

Estimated annual number of responses per respondent: 1.5.

Estimated annual number of responses: 10,800.

Estimated total annual burden on respondents: 4,618 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 8th day of July 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–16612 Filed 7–13–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0099]

Availability of an Environmental Assessment and Finding of No Significant Impact for the Biological Control of Cape-Ivy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared a final environmental assessment and finding of no significant impact relative to the field release of a gall-forming fly, *Parafreutreta regalis,* into the continental United States for the use as a biological control agent to reduce the severity of Cape-ivy, *Delairea odorata.* Based on the finding of no significant impact, we have determined that an environmental impact statement need not be prepared.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Tichenor, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2198.

SUPPLEMENTARY INFORMATION: Cape-ivy (*Delairea odorata*), a native of South Africa, has become one of the most pervasive non-native plants to invade the coastal west region of the United States, particularly in California and Oregon. Cape-ivy is a weedy vine that prefers moist, partly-shaded environments along the Pacific coast; however, there are reports of infestations at inland riparian locations. Fragments of the plant easily root, which facilitates the spread of this invasive plant. Overgrowth of Cape-ivy, a climbing vine, causes native plants to die. The Animal and Plant Health Inspection Service (APHIS) is proposing to issue permits for the field release of a gall-forming fly, *Parafreutreta regalis,* into the continental United States to reduce the severity of Cape-ivy infestations.

On March 24, 2016, we published in the **Federal Register** (81 FR 15679–15680, Docket No. APHIS–2015–0099) a notice[1] in which we announced the availability, for public review and comment, of an environmental assessment (EA) that examined the potential environmental impacts associated with the proposed release of *P. regalis* into the continental United States.

We solicited comments on the EA for 30 days ending April 25, 2016. We received 23 comments by that date. The comments were from a State native plant society, plant preservation entities, State departments of agriculture, an organization of State plant regulatory agencies, and private citizens. Twenty-two commenters supported this action.

One commenter raised a concern about the possibility of *P. regalis* being introduced to Hawaii by airplanes commuting from California to Hawaii and asked whether we considered the biological risks associated with the release of *P. regalis* in Hawaii. We have prepared a response to this specific concern in an appendix to the final EA.

In this document, we are advising the public of our finding of no significant impact (FONSI) regarding the release of *P. regalis* into the continental United States for use as a biological control agent for Cape-ivy. The finding, which is based on the final EA, reflects our determination that release of this biological control agent will not have a significant impact on the quality of the human environment.

The final EA and FONSI may be viewed on *Regulations.gov* Web site (see footnote 1). Copies of the EA and FONSI are also available for public inspection at USDA, Room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead to (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 8th day of July 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–16624 Filed 7–13–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2014–0032]

Establishment-Specific Data Release Strategic Plan

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of its final Establishment-Specific Data Release Strategic Plan (the Plan) for sharing data on federally inspected meat and poultry establishments with the public. FSIS is also responding to comments received on a draft version of the Plan that FSIS posted on its Web site and announced in January 2015 in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) to protect the health and welfare of consumers. The Agency is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, not adulterated, and correctly labeled and packaged.

---

[1] To view the notice, the comments we received, the final EA, and the FONSI, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0099.*

FSIS inspects these products at official slaughtering and processing establishments, verifying that the establishments meet regulatory requirements and enforcing those requirements as necessary.

Additionally, FSIS employees (including inspectors, veterinarians, laboratorians, and Enforcement, Investigations, and Analysis Officers (EIAOs)) perform a variety of activities, including conducting inspections, ensuring compliance with existing regulations, and collecting and testing microbiological and chemical residue samples to verify that establishments are maintaining Hazard Analysis and Critical Control Point (HACCP) plans or other food safety systems that address these hazards.

While conducting these activities and performing many other key functions, FSIS collects a large volume of establishment-specific data. Using the data, FSIS produces reports for internal use, and publicly shares data and reports through the Agency's Web site[1] and other public communication venues. Most of the data that FSIS shares with the public is aggregated or in summary format; however, FSIS releases a large volume of disaggregated, establishment-specific data to the public through formal Freedom of Information Act (FOIA) requests.[2]

In a notice published in the **Federal Register** on January 15, 2015, FSIS announced that the Agency had developed a plan for sharing data on federally inspected meat, poultry, and processed egg product establishments with the public (80 FR 2092). The Agency developed the Plan in response to policy documents issued by President Obama and the Office of Management and Budget (OMB), and to reduce the administrative burden FOIA requests have placed on the Agency.

In 2009, President Obama and OMB released policy documents that called for increased data sharing and greater transparency in Federal agencies, including President Obama's January 21, 2009 "Memorandum on Transparency and Open Government,"[3] OMB's February 24, 2009 memorandum on "The President's Memorandum on Transparency and Open Government—Interagency Collaboration"[4] and OMB's December 8, 2009 "Open Government Directive."[5] President Obama subsequently issued policy documents instructing agencies to develop plans for making information on regulatory compliance and enforcement activities available in machine-readable format, and accessible, downloadable, and searchable online.[6]

Upon the recommendation of the National Advisory Committee on Meat and Poultry Inspection (NACMPI), FSIS asked the National Research Council (NRC) within the National Academies to study the potential food safety benefits and consequences of releasing establishment-specific data to the public. The NRC convened a committee in 2011 and issued a report that analyzed the costs and benefits of releasing establishment-specific data, recommending that FSIS develop a strategic plan to guide the Agency's efforts to release the data.[7]

FSIS also convened an internal committee to conduct its own in-depth review of Federal data sharing procedures and resources, which culminated in the development of the draft version of the Plan. NACMPI reviewed the draft plan in January 2014 and FSIS incorporated its feedback in the announced version of the draft Plan.

Final Revision of the Plan

After carefully reviewing the submitted comments, FSIS made minor changes to the draft Plan. These changes include updated preliminary lists of datasets identified for release and considered for future release, as well as an expanded explanation of how FSIS will determine the level of aggregation for each dataset. The final revision of the Plan can be viewed on the Agency's Web site at *http://www.fsis.usda.gov/wps/wcm/connect/0803f8a0-a3cc-4945-87b6-f992acdcfa9b/Establishment-Specific-Data-Plan-Final.pdf?MOD=AJPERES.*

The Plan establishes FSIS's process for releasing establishment-specific data on *Data.gov.* The Plan includes an overview of FSIS data collection processes and structures, dataset selection criteria, data release procedures, a preliminary list of Agency datasets for public release, and performance measures for evaluating the effectiveness of data release.

The preliminary list of Agency datasets for public release includes a "demographic" dataset of all regulated establishments that incorporates both information currently included in the Meat, Poultry and Egg Product Inspection Directory (name, number, address, grant date, slaughter and/or processing, meat and/or poultry) and additional information to facilitate data analysis (*e.g.,* variables specifically created to allow different datasets to be correctly combined). The preliminary list also includes data on *Listeria monocytogenes* and *Salmonella* in ready-to-eat (RTE) products and processed egg products; data on Shiga Toxin-producing *Escherichia coli* (STEC) and *Salmonella* in raw, non-intact beef products; data on *Salmonella* and *Campylobacter* in young chickens and young turkeys, comminuted poultry, and chicken parts; routine chemical residue testing data in meat and poultry products; and advanced meat recovery (AMR) testing data. Of these, Salmonella in raw, non-intact beef products; Listeria monocytogenes and Salmonella in processed egg products; and Salmonella and Campylobacter in young chickens and young turkeys, comminuted poultry, and chicken parts are new additions to the Plan.

Agency datasets identified for the first release include the demographic dataset and Listeria and Salmonella data in RTE products. FSIS will release these datasets by October 12, 2016. The preliminary list of Agency datasets will not all be released at the same time, and before the release of final datasets, FSIS intends to publish a Constituent Update with a link to a sample dataset for stakeholder review. For each dataset to be released, FSIS will determine and announce, on a case-by-case basis, the appropriate level of aggregation. For example, datasets could be aggregated at the national level or not aggregated at all, depending on FSIS's determination.

---

[1] For more information, please visit: *www.fsis.usda.gov.*

[2] The Freedom of Information Act 5 U.S.C. 552, As Amended by Public Law 104–231, 110 Stat. 3048. Available at: *http://www.justice.gov/oip/amended-foia-redlined.pdf.*

[3] "Transparency and Open Government: Memorandum for the Heads of Executive Departments and Agencies". (74 FR 4685; Jan. 26, 2009), pp. 4685–4686. Available at: *http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment.*

[4] "Memorandum for the Heads of Executive Departments and Agencies: President's Memorandum on Transparency and Open Government—Interagency Collaboration." Memorandum Number: M–09–12. 24 February, 2009. Available at: *http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-12.pdf.*

[5] "Memorandum for the Heads of Executive Departments and Agencies: President's Memorandum on Transparency and Open Government—Interagency Collaboration." Memorandum Number: M–10–06. 8 December, 2009. Available at: *http://www.whitehouse.gov/open/documents/open-government-directive.*

[6] "Memorandum on Regulatory Compliance." 76 FR 3825 (January 21, 2011); "Making Open and Machine Readable the New Default for Government Information." Executive Order 13642. 78 FR 28111 (May 14, 2013).

[7] National Research Council, Committee on a Study of Food Safety and Other Consequences of Publishing Establishment-Specific Data. "The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data." 2011. Available at: *http://www.nap.edu/catalog.php?record_id=13304.*

Besides the preliminary datasets that the Agency intends for release, FSIS is considering additional data sources for future release of both aggregate and individual establishment data. These include: Individual establishment inspection task data associated with verification of compliance with each regulation; humane handling task data; and import sampling task data relating to STEC, *Salmonella,* and residue testing.

The following is a summary of the comments received and FSIS's responses.

Summary of Comments and Responses

FSIS received 19 comments in response to the January 2015 notice. The comments were from trade groups representing the meat and poultry industry, consumer groups, animal welfare groups, veterinary associations, a corporation that produces meat and poultry products, and three private citizens.

National Research Council (NRC) Study

Comment: Several commenters stated that the release of establishment-specific data could damage the reputation of product brands because consumers will relate products to the specific establishments producing those products. These commenters suggested that the data released could create competitive disparity within the industry or cause harm to the U.S. food industry. Because of this, according to the commenters, the release of establishment-specific data would be akin to FSIS's endorsing certain brands over others.

One commenter agreed that some brands may develop an unwanted reputation based on data released to the public, but believed that this could actually benefit FSIS by weeding out bad actors.

Other commenters stated that the Plan will have a limited impact on brand reputation because consumers do not relate products to the specific establishments producing those products.

Response: While consumers could relate brands to the specific establishments producing their products, FSIS will not endorse certain brands over others through sharing data. FSIS maintains information on establishments, not brand information. When evaluating datasets for release, FSIS will thoroughly examine whether releasing datasets could have an adverse impact on the industry, including whether releasing the dataset would create market disparity. However, the NRC Committee thought that one potential benefit of releasing establishment-specific data would be that consumers would be able to make more informed choices, and that resulting consumer pressure could motivate corporations to improve performance in order to protect brand reputation.

Criteria for Evaluating FSIS Datasets for Public Posting

Comment: Some commenters stated that data released under the Plan could contain confidential information such as Personally Identifiable Information (PII), or proprietary information such as trade secrets. Other commenters suggested that the release of certain establishment-specific data to the public could incentivize foreign countries to erect trade barriers against the United States or individual companies. One commenter noted that the release of certain establishment-specific data could expose establishments to vulnerabilities in food defense. The commenter also stated that the publication of the establishment's name, address, and size, along with the types of products produced, could direct potential terrorists to more desirable targets.

Response: FSIS will thoroughly examine candidate datasets, using multiple FSIS personnel, to ensure the datasets do not contain PII, confidential information or proprietary information. The Agency will not release data that contains confidential information, including PII, on either FSIS staff or establishment employees.

In addition, FSIS will consider potential security risks associated with release of data based on the evolving threat landscape. The release of establishment-specific demographic data, such as the name, address, and type of product produced, does not pose a significant security risk to food defense. Most of this information is already available to the public in the Meat, Poultry, and Egg Product Directory. The Agency continues to recommend that establishments voluntarily adopt and implement food defense measures to mitigate potential vulnerabilities.

Comment: Several commenters stated that the release of disaggregated, establishment-specific data may mislead the public if there is a lack of context. For example, the public may misconstrue the meaning and significance of NRs received by establishments if the corrective actions, enforcement actions, and appeals are not also provided. These commenters worried that misinterpretation of the data could be harmful to the image of the individual establishments and the industry as a whole.

Some commenters recommended FSIS adopt a due-process mechanism to prevent the release of data that can be easily misinterpreted. These commenters requested that the industry be allowed to examine data and user guides concerning the data before they are released to the public. One commenter recommended that FSIS incorporate the user guides into the same document containing the datasets to increase the likelihood that the public will consult the guides when reviewing the data. Another commenter recommended that FSIS use consumer test panels to evaluate whether readers understand the data. The same commenter also recommended that FSIS allow the industry to provide comments along with the datasets to help give the public some context in interpreting the data.

Response: FSIS staff will thoroughly evaluate every dataset to determine the potential for misinterpretation. If it is highly likely that the public will misinterpret the released data, the Agency will evaluate the dataset to determine if additional explanatory or contextual information would reduce that likelihood. If additional information will not reduce the potential for misinterpretation, the Agency will remove the dataset from consideration for release.

In addition, the Plan provides a thorough list of context-providing documentation that will be included in user guides with each dataset released, including: (1) A dataset overview and explanation; (2) database-specific dictionaries; (3) historical information on changes to sampling methods and scheduling or collection to inform changes to time-series; (4) the context in which the data was collected; (5) sources of variability and specificity of methods used; (6) the dataset's relationship to other released datasets; (7) data use limitations; and (8) links to analyses conducting using the data to be released. FSIS will share these user guides with industry stakeholders prior to the release of datasets to ensure the accuracy of the information; however, there is no plan at this time to include industry comments with the released datasets.

Comment: Some commenters stated that the Plan did not articulate how the release of establishment-specific data aligns with FSIS's goals. Specifically, these commenters requested that FSIS articulate how each data release aligns with a public health objective.

Response: Every dataset released will align with the primary mission of FSIS:

To ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Because of its importance, for every dataset it considers for release, FSIS will separately evaluate whether the data released will be used to benefit the public's health and reduce foodborne illness.

Comment: Some commenters expressed concern about the potential cost for the Agency to implement the Plan. One commenter stated that too many FSIS resources would be expended in implementing the Plan and requested the inclusion of additional information about cost savings.

Response: The monetary and personnel costs associated with implementing the Plan will be minimal. Under the Plan, FSIS will consider both the Agency's personnel and monetary costs when determining which datasets to release. Accordingly, data that will create a heavy administrative burden through excessive documentation or manual redaction will not be released. To further reduce the administrative costs, FSIS will develop an automated algorithm that will identify and collect datasets intended for release.

Prioritization for Data Release

Comment: Several commenters identified additional datasets that should be considered for release, such as import inspection data, humane handling task data, Food-Safety Assessments (FSAs), codes for inspections tasks that were not performed and whether establishments participate in the new poultry inspection system.

A few commenters requested the release of information on tissue residue violations in cull dairy cows. These commenters stated that the information, which was published on the Agency's Web site until March 2011, is a valuable resource for the dairy industry to target outreach efforts and reduce the probability that repeat violations will occur.

Response: After considering these comments, FSIS has decided to add import inspection data, FSAs, and inspection tasks that were not performed to the preliminary list of data sources to be considered for future release. Humane handling task data is already on the preliminary list. FSA data will be limited to exclude free-text fields that may include PII or proprietary information.

FSIS announced in the 2016 **Federal Register** Notice titled "New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts . . ." that it will begin posting, based on FSIS sampling results and depending on the standard for the particular product, whether an establishment meets the FSIS pathogen reduction performance standards, or what category an establishment is in.

FSIS does not intend to resume the publication of a monthly Residue Violator List that includes the name of any producer with at least one residue violation in the previous 12-months. The Agency stopped publishing the monthly Residue Violator List in 2011 to prevent potential economic harm to producers with only one violation. Instead, FSIS will continue to publish a weekly Residue Repeat Violator List, which identifies producers with multiple residue violations within a 12-month period.[8] FSIS notes that many first time violators do not go on to become repeat violators within the designated 12-month period. In addition, repeat violators have an incentive to improve operations and prevent violative residues in order to remove their names from the Repeat Violator List.

Comment: A few commenters requested that FSIS release noncompliance records (NRs) filed by FSIS inspection personnel, subsequent appeals, and their eventual resolutions. Several commenters requested that NRs not be released because consumers could easily misinterpret their significance and regulatory meaning. Those same commenters argued that it would waste FSIS resources to review and redact each NR before releasing the data.

Response: FSIS does not intend to release NRs as a stand-alone data set at this time. FSIS will consider releasing the compliance status of individual inspection tasks and regulations if FSIS decides to release inspection task data in the future. Free-text fields will never be released because of the possible presence of PII and because manual redaction is costly. However, general information, such as whether or not an NR was recorded, the date the NR was issued, which regulations it cited, whether an appeal was filed, and whether the appeal was granted, will be considered for release.

Comment: One commenter encouraged FSIS to release historical data from older data systems in addition to the Public Health Information System (PHIS) data it currently plans to release.

Response: At this time, only data collected since the implementation of PHIS in 2012 will be considered for release. The historical data from before the implementation of PHIS would be too burdensome for the Agency to release. FSIS will consider releasing historical data from older data systems at a later date if Agency resources permit.

Data Release Procedures

Comment: One commenter asked that FSIS release data more frequently than on a quarterly basis. The commenter stated that because PHIS collects data in real time, FSIS should be able to release data every month.

Response: At this time, one new dataset from the Priority List is scheduled to be released no more frequently than on a quarterly basis. This will provide the Agency sufficient time to select and verify the accuracy of the data, as well as release a sample data set and documentation through an FSIS Constituent Update to interested stakeholders for review.

Comment: Some commenters recommended that FSIS "blind" or aggregate the datasets. The blind or aggregated data would allow interested parties to see how industry and the Agency are performing in various areas without compromising individual companies and creating market disparity.

Response: As part of the review process, FSIS will determine the most appropriate level of aggregation for each dataset. FSIS will continue to release at a national level of aggregation datasets that are currently so aggregated. For other datasets, FSIS intends to assess feedback from stakeholders and other users of the data to determine if additional levels of aggregation would be useful. Also, for each dataset planned for initial release, FSIS plans to release establishment-specific information, including the establishment's name and number.

Measurement of Effectiveness of Data Release

Comment: One commenter stated that some of the metrics presented in the draft Plan to measure effectiveness are too narrow to fully capture the ways in which the data is used. For instance, according to the commenter, a metric for the number of presentations on related data by FSIS staff at professional meetings does not account for presentations on other topics that use the data as a portion of their presentations. Similarly, the commenter stated that a metric for the number of peer-reviewed reports generated using the establishment-specific data does not include papers that use the data that are not peer-reviewed.

---

[8] The FSIS Repeat Residue Violator List can be downloaded at *http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry.*

Another commenter recommended that FSIS reassess the Plan after one year. If after one year FSIS determines that the data release program is not achieving its intended goals, the Agency should change the Plan.

Response: FSIS acknowledges that it is impossible to anticipate every way in which the released establishment-specific data will be used. The Plan, however, presents a framework of performance measures that will adequately inform future data releases. This framework includes a combination of the seven quantitative metrics listed, along with qualitative measures, such as assessments of how data are interpreted and used by stakeholders. FSIS will regularly review these metrics and use them to guide future choices for data release.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture Director,
Office of Adjudication, 1400
Independence Avenue SW.,
Washington, DC 20250–9410.

Fax

(202) 690–7442

Email

program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720–2600 (voice and TDD).

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/federal-register.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on July 11, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–16642 Filed 7–13–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Institute of Standards and Technology (NIST).

Title: NIST Associates Information System (NAIS).

OMB Control Number: 0693–0067.

Form Number(s): None.

Type of Request: Regular submission (extension).

Number of Respondents: 4,000.

Average Hours per Response: 30 minutes.

Burden Hours: 2,000.

Needs and Uses: NIST Associates (NA) will include guest researchers, research associates, contractors, and other non-NIST employees that require access to the NIST campuses or resources. The NIST Associates Information System (NAIS) information collection instruments(s) are completed by incoming NAs. They are asked to provide personal identifying data including home address, date and place of birth, employer name and address, and basic security information. The data provided by the collection instruments is input into NAIS which automatically populates the appropriate forms, and is routed through the approval process. NIST's Office of Security receives security forms through the NAIS process and is able to allow preliminary access to NIST for NAs. The data collected is the basis for further security investigations as necessary.

Affected Public: Individuals or households.

Frequency: Once.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: July 8, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–16600 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results, Partial Rescission of Antidumping Duty Administrative Review, and Preliminary Rescission of New Shipper Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) is conducting an administrative review (AR) and a new shipper review (NSR) of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished (TRBs), from the People's Republic of China (PRC). The AR covers four [1] exporters, of which

---

[1] This figure does not include one exporter for which the Department is preliminarily rescinding the administrative review.

the Department selected two mandatory respondents for individual examination (*i.e.*, Changshan Peer Bearing Co. Ltd. (CPZ/SKF); and Yantai CMC Bearing Co., Ltd. (Yantai CMC)). The NSR covers Shandong Bolong Bearing Co., Ltd. (Bolong). The period of review (POR) is June 1, 2014, through May 31, 2015.

We preliminarily determine that sales of subject merchandise have been made below normal value (NV). In addition, we preliminarily determine that Bolong's sale to the United States is not *bona fide*, as required by section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act).[2] Therefore, we are preliminarily rescinding this NSR. If these preliminary results are adopted in the final results of this review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Blaine Wiltse or Manuel Rey, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6345 or (202) 482–5518, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise covered by the order includes tapered roller bearings and parts thereof. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the order is dispositive.[3]

Tolling of Deadlines for Preliminary Results

As explained in the memorandum from the Acting Assistant Secretary for Enforcement and Compliance, the Department exercised its discretion to toll all administrative deadlines for the duration of the closure of the Federal Government during Snowstorm "Jonas." [4] Therefore, all deadlines in this segment of the proceeding have been extended by four days. The revised deadline for the preliminary results of this review is now July 5, 2016.

Partial Rescission of the Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. On October 27, 2015, GGB Bearing Technology (Suzhou) Co., Ltd. (GGB) timely withdrew its request for an administrative review.[5] No other party had requested a review of GGB. Based on the timely withdrawal of the request for review and because GGB established its entitlement to a separate rate from a prior segment, the Department is rescinding this administrative review with respect to GGB, in accordance with 19 CR 351.213(d)(1).

Preliminary Rescission of the NSR

As discussed in the Bona Fides Analysis Memorandum,[6] the Department preliminarily finds that the single sale made by Bolong to the United States during the POR is not a *bona fide* sale. The Department reached this conclusion based on the totality of the circumstances surrounding the reported sale, including:

> (I) the prices of such sales; (II) whether such sales were made in commercial quantities; (III) the timing of such sales; (IV) the expenses arising from such sales; (V) whether the subject merchandise involved in such sales was resold in the United States at a profit; (VI) whether such sales were made on an arms-length basis; and (VII) any other factor {it} determines to be relevant as to whether such sales are, or are not, likely to be typical of those the exporter or producer will make after completion of the review.[7]

Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, and thus there are no reviewable transactions on this record, we are preliminarily rescinding the NSR. Because much of the factual information used in our analysis of Bolong's sale involves business proprietary information, a full discussion of the basis for our preliminary determination is set forth in the Bona Fides Analysis Memorandum.

We further note that Bolong's NSR request did not conform to the Department's regulations at 19 CFR 351.214(b)(2)(ii). 19 CFR 351.214(b)(2)(ii) requires that, in order to qualify for a NSR, the requestor must provide certifications from both itself and any company that supplied it with subject merchandise that neither party exported the subject merchandise to the United States during the period of investigation. In this case, Bolong purchased in-scope components from unaffiliated producers, and it failed to provide the certifications required by 19 CFR 351.214(b)(2)(ii) from those producers. The Department requires appropriate certifications from any company requesting a NSR that sources in-scope merchandise, whether finished or unfinished, from its suppliers. In conjunction with any arguments that its reported sale is *bona fide*, Bolong shall submit the requisite certifications from the suppliers of the subject merchandise.

Methodology

The Department is conducting this review in accordance with section 751(a)(1)(B) of the Act. As noted above, there are two mandatory respondents in this administrative review: CPZ/SKF and Yantai CMC. For CPZ/SKF, we calculated constructed export prices in accordance with section 772 of the Act. Because the PRC is a non-market economy (NME) within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act.

For Yantai CMC, we preliminarily find that this respondent is ineligible for a separate rate because it has failed to demonstrate an absence of *de facto* government control in this administrative review. Therefore, we did not calculate a separate margin for Yantai CMC.

---

[2] On February 24, 2016, the President of the United States signed into law the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114–125 (February 24, 2016), which made amendments to section 751(a)(2)(B) of the Act. These amendments apply to this determination.

[3] For a complete description of the scope of the order, *see* memorandum from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, entitled "Decision Memorandum for the Preliminary Results of the 2014–2015 Antidumping Duty Administrative Review and New Shipper Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China" (Preliminary Decision Memorandum), issued concurrently with and hereby adopted by this notice.

[4] *See* Memorandum to the Record from Ron Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During Snowstorm Jonas," dated January 27, 2016.

[5] *See* Letter to the Department from GGB, "Withdrawal of Administrative Review Request in the Antidumping Duty Order on Tapered Roller Bearings from the People's Republic of China (POR: 06/01/14–5/31/15)," dated October 27, 2015.

[6] *See* Memorandum from Manuel Rey, International Trade Analyst, to Melissa Skinner, Director of AD/CVD Operations, dated July 5, 2016 entitled, "New Shipper Review of Tapered Roller Bearings and Parts Thereof from the People's Republic of China—Bona Fides Sales Analysis" (Bona Fides Analysis Memorandum), issued concurrently with and hereby adopted by this notice.

[7] *See* section 751(a)(2)(B)(iv) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as the Appendix to this notice.

Rate for Non-Examined Companies Which Are Eligible for a Separate Rate

As indicated in the "Preliminary Results of Review" section below, we preliminarily determine that a margin of zero percent applies to the two firms not selected for individual review but determined to be eligible for a separate rate. For further information, *see* the Preliminary Decision Memorandum at "Rate for Non-Examined Companies Which Are Eligible for a Separate Rate."

Preliminary Results of Review

Because Yantai CMC did not demonstrate that it was entitled to a separate rate, the Department preliminarily finds Yantai CMC to be part of the PRC-wide entity.[8] The rate previously established for the PRC-wide entity is 92.84 percent.

The Department preliminarily determines that the following weighted-average dumping margins exist for the period June 1, 2014, through May 31, 2015:

Exporters	Weighted-average percent margin
Changshan Peer Bearing Co., Ltd	0.00
Haining Nice Flourish Auto Parts Co., Ltd *	0.00
Roci International (HK) Limited *	0.00

* This company demonstrated that it qualified for a separate rate in this administrative review.

Disclosure and Public Comment

The Department will disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[9] Rebuttals to case briefs may be filed no later than five days after case briefs are filed and all rebuttal briefs must be limited to comments raised in the case briefs.[10] Parties who submit comments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11]

Any interested party may request a hearing within 30 days of publication of this notice.[12] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.[13] If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.[14]

All submissions, with limited exceptions, must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.

Unless otherwise extended, the Department intends to issue the final results of this administrative review, which will include the results of its analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of the administrative review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[15] If the preliminary results are unchanged for the final results we will instruct CBP to apply an *ad valorem* assessment rate of zero percent to all entries of subject merchandise during the zero percent to all entries of subject merchandise during the POR which were produced and/or exported by CPZ/SKF and the two aforementioned companies which were not selected for individual examination but were found to be eligible for a separate rate.

If we determine in the final results that an individually-examined respondent in the administrative review (*e.g.,* CPZ/SKF) has a weighted-average dumping margin which is not zero or *de minimis* (*i.e.,* less than 0.5 percent), then we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1).[16]

For the final results, if we continue to treat Yantai CMC as part of the PRC-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 92.84 percent to all entries of subject merchandise during the POR which were exported by Yantai CMC.

We intend to issue assessment instructions to CBP 15 days after the publication of the final results of this review.

For entries that were not reported in the U.S. sales databases submitted by companies individually examined during the administrative review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.*, at that exporter's rate) will be liquidated at the PRC-wide rate.[17]

---

[8] *See* Preliminary Decision Memorandum, at 8–10. Pursuant to the Department's change in practice, the Department no longer considers the NME entity as an exporter conditionally subject to administrative reviews. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013). Under this practice, the NME entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the entity, the entity is not under review and the entity's rate is not subject to change.

[9] *See* 19 CFR 351.309(c)(1)(ii).

[10] *See* 19 CFR 351.309(d).

[11] *See* 19 CFR 351.309(c)(2).

[12] *See* 19 CFR 351.310(c).

[13] *Id.*

[14] *See* 19 CFR 351.310(d).

[15] *See* 19 CFR 351.212(b)(1).

[16] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

If we proceed to a final rescission of the NSR, Bolong's entries will be assessed at the rate entered.[18] If we do not proceed to a final rescission of the NSR, pursuant to 19 CFR 351.212(b)(1), we will calculate an importer-specific assessment rate for Bolong. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this NSR if the importer-specific assessment rate calculated in the final results of this NSR is above *de minimis.*[19]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above which have a separate rate, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* then a cash deposit rate of zero will be established for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the PRC-wide entity, 92.84 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Effective upon publication of the final rescission or the final results of the NSR, pursuant to section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e), the Department will instruct CBP to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise by Bolong. If the Department proceeds to a final rescission of the NSR, the cash deposit rate will continue to be the PRC-wide rate for Bolong because the Department will not have determined an individual margin of dumping for this company. If the Department issues final results for the NSR, the Department will instruct CBP to collect a cash deposit, effective upon the publication of the final results, at the rate established therein.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these preliminary results of reviews in accordance with sections 751(a)(l), 751(a)(2)(B) and 777(i)(l) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 5, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Bona Fides Analysis
5. Discussion of the Methodology for the Administrative Review
   a. Non-Market Economy Country
   b. Separate Rates
   c. Separate Rate Assigned to Non-Selected Companies
   d. The PRC-Wide Entity
   e. Collapsing of CPZ/SKF With Another Producer of TRBs
   f. Surrogate Country
   g. Date of Sale
   h. Comparisons to Normal Value
   i. Determination of Comparison Method
   j. Constructed Export Price
   k. Value-Added Tax (VAT)
   l. Normal Value
   m. Currency Conversion
6. Conclusion

[FR Doc. 2016–16467 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE693

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Cost Recovery Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of fee percentage.

SUMMARY: NMFS publishes notification of a 1.60 percent fee for cost recovery under the Bering Sea and Aleutian Islands Crab Rationalization Program. This action is intended to provide holders of crab allocations with the fee percentage for the 2016/2017 crab fishing year so they can calculate the required payment for cost recovery fees that must be submitted by July 31, 2017.

DATES: The Crab Rationalization Program Registered Crab Receiver permit holder is responsible for submitting the fee liability payment to NMFS on or before July 31, 2017.

FOR FURTHER INFORMATION CONTACT: Keeley Kent, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

NMFS Alaska Region administers the Bering Sea and Aleutian Islands Crab Rationalization Program (Program) in the North Pacific. Fishing under the Program began on August 15, 2005. Regulations implementing the Program can be found at 50 CFR part 680.

The Program is a limited access system authorized by section 313(j) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Program includes a cost recovery provision to collect fees to recover the actual costs directly related to the management, data collection, and enforcement of the Program. The Program implemented under the authority of section 313(j) is consistent with the cost recovery provisions included under section 304(d)(2)(A) of the Magnuson-Stevens Act. NMFS developed the cost recovery provision to conform to statutory requirements and to reimburse the agency for the actual costs directly related to the management, data collection, and enforcement of the Program. The cost recovery provision allows collection of 133 percent of the actual management, data collection, and enforcement costs up to 3 percent of the ex-vessel value of crab harvested under the Program. The Program provides that a proportional share of fees charged for management and enforcement be forwarded to the State of Alaska for its share of management and data collection costs for the Program. The cost recovery provision also requires the harvesting and processing sectors to each pay half the cost recovery fees. Catcher/processor quota shareholders are required to pay the full fee percentage for crab processed at sea.

---

[17] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

A crab allocation holder generally incurs a cost recovery fee liability for every pound of crab landed. The crab allocations include Individual Fishing Quota, Crew Individual Fishing Quota, Individual Processing Quota, Community Development Quota, and the Adak community allocation. The Registered Crab Receiver (RCR) permit holder must collect the fee liability from the crab allocation holder who is landing crab. Additionally, the RCR permit holder must collect his or her own fee liability for all crab delivered to the RCR. The RCR permit holder is responsible for submitting this payment to NMFS on or before July 31, in the year following the crab fishing year in which landings of crab were made.

The dollar amount of the fee due is determined by multiplying the fee percentage (not to exceed 3 percent) by the ex-vessel value of crab debited from the allocation. Specific details on the Program's cost recovery provision may be found in the implementing regulations at 50 CFR 680.44.

Fee Percentage

Each year, NMFS calculates and publishes in the **Federal Register** the fee percentage according to the factors and methodology described in Federal regulations at § 680.44(c)(2). The formula for determining the fee percentage is the "direct program costs" divided by "value of the fishery," where "direct program costs" are the direct program costs for the Program for the previous fiscal year, and "value of the fishery" is the ex-vessel value of the catch subject to the crab cost recovery fee liability for the current year. Fee collections for any given year may be less than, or greater than, the actual costs and fishery value for that year, because, by regulation, the fee percentage is established in the first quarter of a crab fishery year based on the fishery value and the costs of the prior year.

Based upon the fee percentage formula described above, the estimated percentage of costs to value for the 2015/2016 fishery was 1.60 percent. Therefore, the fee percentage will be 1.60 percent for the 2016/2017 crab fishing year. This is an increase of 0.12 percent from the 2015/2016 fee percentage of 1.48 percent (80 FR 42792, July 20, 2015). The change in the fee percentage from 2015/2016 to 2016/2017 is due to an increase in Alaska Department of Fish and Game management costs. These additional costs were necessary to process, analyze, and report fishery data for monitoring and management of the crab fisheries in the Program. Additionally, the value of crab harvested under the Program decreased by $1.6 million. This decrease in value of the fishery contributed to the increase in the fee percentage between 2015/2016 and 2016/2017.

Authority: 16 U.S.C. 1862; Pub. L. 109–241; Pub. L. 109–479.

Dated: July 11, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16655 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE691

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. The Exempted Fishing Permit would allow one commercial fishing vessel to fish outside of the summer flounder, scup, and black sea bass regulations in support of research conducted by the Cornell Cooperative Extension. These exemptions would enable research designed to quantify codend mesh selectivity for summer flounder, black sea bass, and scup.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before July 29, 2016.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line "CCE FSB mesh selectivity EFP."
- *Mail:* John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on CCE FSB mesh selectivity EFP."
- *Fax:* (978) 281–9135.

FOR FURTHER INFORMATION CONTACT: Elizabeth Scheimer, Fisheries Management Specialist, 978–281–9236.

SUPPLEMENTARY INFORMATION: Cornell Cooperative Extension (CCE) submitted a complete application for an Exempted Fishing Permit (EFP) on June 6, 2016. They are seeking regulatory exemptions to allow gear research to be conducted on a commercial vessel fishing for a project funded by the Mid-Atlantic Fishery Management Council's collaborative research initiative. The EFP would authorize exemptions from the minimum mesh size and net modification requirements found at 50 CFR 648.108, 648.125, and 648.144. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited, including landing fish in excess of a possession limit or below the minimum size.

Experimental fishing activity would compare the composition, commercial yield, retention efficiency, discards, and size selectivity of five different codends in the summer flounder, scup, and black sea bass commercial bottom trawl fishery in the Mid-Atlantic. The current regulated mesh sizes are 5.5-inch (13.97-cm) diamond or 6-inch (15.24-cm) square for summer flounder, 5-inch (12.7-cm) diamond for scup, and 4.5-inch (11.43-cm) diamond for black sea bass. This project would test diamond mesh in 4.5-inch (11.43-cm), 5-inch (12.7-cm), 5.5-inch (13.97-cm), 6-inch (15.24-cm), and 6-inch (15.24-cm) square mesh.

The research would be conducted on a commercial fishing vessel using a trouser trawl that would allow an experimental codend and the control codend to be fished at the same time. The control codend would be a standard squid liner with 6-cm diamond mesh.

The researchers would conduct the experiment across the wide range of strata and conditions representative of this fishery. Tow speeds, tow cable scope, and tow cable length would be consistent across all tows. The researchers propose to conduct 20 tows per experimental codend, for a total of 100 tows. Up to 20 days of fishing would occur between August 15 and December 31, 2016, south of Block Island and Long Island, in statistical areas 539, 613, 612, and 611. The researchers would not fish in the scup gear restricted areas or the Summer Flounder Fishery Sea Turtle Protection Area. Onboard catch processing would follow NMFS trawl survey standards. Total summer flounder, black sea bass, and scup would be weighed for each tow. Researchers will target a minimum of 200 random length measurements of each species to be sampled for each tow, but if fewer individuals are caught then all would be measured. CCE's anticipated catch is shown in table 1.

TABLE 1—TOTAL ESTIMATED CATCH FOR 100 TOWS DURING MESH SELECTIVITY STUDY

Species	Legal	Sub-legal
Summer Flounder	18,000 lb (8.1 mt)	9,000 lb (4.0 mt).
Black Sea Bass	27,000 lb (12.2 mt)	13,500 lb (6.1 mt).
Scup	50,000 (22.7 mt)	25,000 lb (11.3 mt).
Incidental Catch:		
Skates	30,000 lb (13.6 mt).	
Dogfish spiny & smooth	30,000 lb (13.6 mt).	
Whiting (silver hake)	30,000 lb (13.6 mt).	
Ling (red hake)	15,000 lb (6.8 mt).	
Squid (longfin)	10,000 lb (4.5 mt).	

CCE would contract one commercial fishing vessel that is licensed for summer flounder, scup, and black sea bass in both New Jersey and New York. Fish would be landed and sold according to the appropriate state limits and be applied against the applicable annual catch limit. CCE would direct all experimental fishing activities that would occur under this EFP. This exemption may increase bycatch numbers beyond those that would normally occur within the fishery; however, the additional mortality will not exceed any catch limits and is therefore negligible. Bycatch will be returned to the water as quickly as possible to reduce mortality.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 11, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–16675 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board; Meetings

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Time and Date: The meeting will be held Tuesday August 2 from 9:15 a.m. CDT to 5:30 p.m. CDT and on Wednesday August 3 from 8:15 a.m. CDT to 1:30 p.m. CDT. These times and the agenda topics described below are subject to change. Please refer to the Web page *http://www.sab.noaa.gov/Meetings/meetings.html* for the most up-to-date meeting times and agenda.

Place: The meeting will be held at the Bryant Conference Center, 240 Paul W. Bryant Dr., Tuscaloosa, Alabama. Please check the SAB Web site *http://www.sab.noaa.gov/Meetings/meetings.html* for directions to the meeting location.

Status: The meeting will be open to public participation with a 15-minute public comment period on August 2 from 12:30–12:45 p.m. CDT (check Web site to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of two (2) minutes. Individuals or groups planning to make a verbal presentation should contact the SAB Acting Executive Director by July 26, 2016 to schedule their presentation. Written comments should be received in the SAB Executive Director's Office by July 26, 2016, to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after July 26, 2016, will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first-served basis.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12:00 p.m. on July 26, 2016, to Dr. Cynthia Decker, SAB Executive Director, SSMC3, Room 11230, 1315 East-West Highway, Silver Spring, MD 20910; Email: *Cynthia.Decker@noaa.gov.*

Matters To Be Considered: The meeting will include the following topics: (1) Report on Arctic Research Review from the Ecosystem Sciences and Management Working Group; (2) Updates from the NOAA Administrator and Chief Scientist; (3) NOAA Response to the SAB GOES–R Level 0 Data report; (4) SAB Strategy Discussion and Implications for NOAA; (5) Discussion of SAB Issue Papers; and (6) Discussion of Working Group and SAB Concepts of Operations.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, Room 11230, 1315 East-West Highway, Silver Spring, MD 20910. Email: *Cynthia.Decker@noaa.gov;* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov.*

Dated: July 8, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–16683 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0084]

Agency Information Collection Activities; Comment Request; Student Aid Internet Gateway (SAIG) Enrollment Document

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 12, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0084. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Aid Internet Gateway (SAIG) Enrollment Document.

OMB Control Number: 1845–0002.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 65,071.

Total Estimated Number of Annual Burden Hours: 14,720.

Abstract: Enrollment in the Federal Student Aid (FSA) Student Aid Internet Gateway (SAIG) allows eligible entities to securely exchange title IV, Higher Education Act (HEA) assistance programs data electronically with the Department of Education processors. Organizations establish Destination Point Administrators (DPAs) to transmit, receive, view and update student financial aid records using telecommunication software. Eligible respondents include, but are not limited to, the following institutions of higher education that participate in title IV, HEA assistance programs, third-party servicers of eligible institutions, Guaranty Agencies, Federal Family Education Loan Program (FFELP) lenders, Federal Loan Servicers, and local educational agencies (LEAs). The Enrollment Form for Post-Secondary Schools and Servicers represents the full complement of questions that must be presented for an organization enrolling in SAIG. The Enrollment Form for State Grant Agencies is a subset of selected questions (from the full complement of questions) to streamline the form for ease of use. This request represents the full 3 year review.

Dated: July 11, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–16645 Filed 7–13–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–433]

Grand River Dam Authority; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of Article 401 reservoir elevation rule curve in order to keep reservoir levels in the Grand Lake O' the Cherokees (Grand Lake) higher than normal from August 16 through October 31. As explained in (k) below, this notice only seeks comments, motions to intervene, and protests on a temporary variance from the rule curve, for the period from August 16 through October 31, 2016.

b. *Project No.:* 1494–433.

c. *Date Filed:* May 6, 2016; supplemented June 2, 2016 and June 30, 2016.

d. *Applicant:* Grand River Dam Authority (GRDA).

e. *Name of Project:* Pensacola Hydroelectric Project.

f. *Location:* The project is located on the Grand River in Craig, Delaware, Mayes, and Ottawa Counties, Oklahoma.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Tamara E. Jahnke, Assistant General Counsel, Grand River Dam Authority, P.O. Box 409, Vinita, OK 74301–0409; telephone: (918) 256–5545.

i. *FERC Contact:* Linda Stewart, telephone (202) 502–6680, email *linda.stewart@ferc.gov;* or B. Peter Yarrington, telephone (202) 502–6129, email *peter.yarrington@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is 14 days from the issuance date of this notice by the Commission.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail a copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–1494–433) on any comments or motions filed.

k. *Description of Request:* In its application, GRDA requests a permanent amendment of the project's Article 401 reservoir elevation rule curve to go into effect August 16, 2016, and remain in effect through the remaining term of the project license. GRDA requests, if a permanent amendment cannot be reviewed by the Commission by August 16, 2016, that a temporary variance for August 16 through October 31, 2016 only be considered while the Commission continues to process its request for a permanent amendment. This notice only seeks comments, motions to intervene, and protests on GRDA's request for a temporary variance for the period from August 16 through October 31, 2016.

GRDA indicates that it seeks the rule curve change to reduce the risk of vessel groundings at Grand Lake in late summer, improve recreation during a peak recreation season, better balance competing stakeholder interests, and provide additional water storage so that, in the event of drought, water would be available for release to aid in maintaining water quality in the river downstream.

Under GRDA's proposal, between August 16 and September 15, the reservoir would be maintained at elevation 743 feet Pensacola Datum (PD), which is up to two feet higher than the current rule curve. Between September 16 and September 30, the elevation would be lowered from 743 to 742 feet PD. Between October 1 and October 31, the reservoir would be maintained at elevation 742 feet PD, which is up to one foot higher than the current rule curve. After October 31, reservoir elevations would follow the project's current rule curve. With its application, GRDA includes a Storm Adaptive Management Plan that would be followed to address high water conditions upstream and downstream of Grand Lake during major precipitation events in the river basin. GRDA also includes a Drought Adaptive Management Plan that would be followed to determine project operation, including deviations from the rule curve elevations, to allow releases for maintenance of downstream water quality and reliable operation of GRDA's downstream Salina Pumped Storage Project if certain drought conditions occur.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. A copy is also available for inspection and reproduction at the address in item (h) above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16652 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13318–003]

Swan Lake North Hydro LLC; Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meetings and Environmental Site Review and Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with Commission and is available for public inspection:

a. *Type of Application:* Original Major License.

b. *Project No.:* 13318–003.

c. *Date filed:* October 28, 2015.

d. *Applicant:* Swan Lake North Hydro LLC.

e. *Name of Project:* Swan Lake North Pumped Storage Hydroelectric Project.

f. *Location:* Approximately 11 miles northeast of the city of Klamath Falls, Klamath County, Oregon. The proposed project would include about 730 acres of federal land managed by the U.S. Bureau of Land Management and the U.S. Bureau of Reclamation.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Joe Eberhardt, EDF–Renewable Energy, 1000 SW Broadway Ave., Ste. 1800, Portland, OR 97205; phone: (503) 889–3838.

i. *FERC Contact:* Dianne Rodman, *dianne.rodman@ferc.gov,* (202) 502–6077.

j. *Deadline for filing scoping comments:* September 9, 2016.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13318–003.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. The proposed project would be a closed-loop system using groundwater for initial fill and consist of the following new facilities: (1) A 7,972-foot-long earthen embankment forming a geomembrane-lined upper reservoir with a surface area of 64.21 acres and a storage capacity of 2,568 acre-feet at a maximum surface elevation of 6,135 feet above mean sea level (msl); (2) a 8,003-foot-long earthen embankment forming a geomembrane-lined lower reservoir with a surface area of 60.14 acres and a storage capacity of 3,206 acre-feet at a maximum surface elevation of 4,457 feet msl; (3) a 500-foot-long, rip-rap lined trapezoidal spillway built into the crest of each embankment; (4) a 0.5-percent slope perforated polyvinyl chloride tube of varying diameter and accompanying optical fiber drainage system designed to detect, collect, and monitor water leakage from the reservoirs; (5) a 25-inch-diameter bottom outlet with manual valve for gravitational dewatering of the lower reservoir; (6) an upper intake consisting of a bell mouth, 38.6-foot-wide by 29.8-foot-long inclined screen, head gate, and 13.8-foot-diameter foundational steel pipe; (7) a 36.5-foot-diameter, 9,655-foot-long steel high-pressure penstock from the upper reservoir to the powerhouse that is predominantly above ground with a 14-foot-long buried segment; (8) three 9.8-foot-diameter, 1,430-foot-long steel low-pressure penstocks from the lower reservoir to the powerhouse that are predominantly above ground with a 78-foot-long buried segment; (9) a partially-buried powerhouse with three 131.1-megawatt (MW) reversible pump-turbine units with a total installed capacity of 393.3 MW; (10) a fenced substation next to the powerhouse; (11) 32.8 mile, 230-kilovolt above-ground transmission line interconnecting to an existing non-project substation; (12) approximately 10.7 miles of improved project access road; (13) approximately 3.4 miles of new permanent project access road; (14) approximately 8.3 miles of temporary project access road; and (15) appurtenant facilities. The project would generate about 1,187 gigawatt-hours annually.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Scoping Process.* The Commission intends to prepare an Environmental Impact Statement (EIS) on the project in accordance with the National Environmental Policy Act. The EIS will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one agency scoping meeting and one public meeting. The agency scoping meeting will focus on resource agency and non-governmental organization (NGO) concerns, while the public scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EIS. The times and locations of these meetings are as follows:

Agency Scoping Meeting

DATE: Wednesday, August 10, 2016.
TIME: 9:00 a.m.
PLACE: Mt. Scott Room.
ADDRESS: College Union, Oregon Institute of Technology, 3201 Campus Drive, Klamath Falls, OR 97601.

Public Scoping Meeting

DATE: Tuesday, August 9, 2016.
TIME: 7:00 p.m.
PLACE: Mt. Mazama Room.
ADDRESS: College Union, Oregon Institute of Technology, 3201 Campus Drive, Klamath Falls, OR 97601.

Copies of the Scoping Document (SD1) outlining the subject areas to be addressed in the EIS were distributed to the parties on the Commission's mailing list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link (see item m above).

Environmental Site Review

The Applicant and FERC staff will conduct a project Environmental Site Review beginning at 9:00 a.m. on August 9, 2016. All interested individuals, organizations, and agencies are invited to attend. All participants should meet at the Edgewood Ranch, 12501 Swan Falls Road, Klamath Falls, Oregon. To reach the ranch from Main Street in Klamath Falls, follow Oregon 39 South/Crater Lake east and south of town. Follow signs for a slight left turn onto Oregon 140 East and follow it for 9.4 miles to Swan Lake Road. Follow Swan Lake Road for 9.4 miles. Edgewood Ranch is located off a driveway at the corner of a 90-degree left-land turn in Swan Lake Road. The main office building is located immediately on the right. Parking is available at the entry driveway before the main office building. Anyone with questions about the Environmental Site Review should contact Joe Eberhardt of EDF–Renewable Energy at (503) 889–3838.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EIS; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EIS, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EIS; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings will be recorded by a stenographer and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EIS.

Dated: July 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16651 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1887–000]

Apple Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Apple Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 28, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 8, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16664 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–1050–000.
Applicants: Texas Eastern Transmission, LP.
Description: Section 4(d) Rate Filing: Negotiated Rates—Sequent Energy Contract 911362 to be effective 7/1/2016.
Filed Date: 6/29/16.
Accession Number: 20160629–5088.
Comments Due: 5 p.m. ET 7/11/16.

Docket Numbers: RP16–1051–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Section 4(d) Rate Filing: Vol 2—Non-Conforming Agreement—Chesapeake Energy Marketing, Inc.—Amendment to be effective 7/1/2016.
Filed Date: 6/29/16.
Accession Number: 20160629–5173.
Comments Due: 5 p.m. ET 7/11/16.

Docket Numbers: RP16–1052–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Section 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Jul 2016 to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5001.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1053–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Section 4(d) Rate Filing: Rock Springs Expansion Initial Rate Filing to be effective 8/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5025.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1054–000.
Applicants: Dominion Transmission, Inc.
Description: Section 4(d) Rate Filing: DTI—June 30, 2016 Negotiated Rate Agreement to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5030.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1055–000.
Applicants: Questar Overthrust Pipeline Company.
Description: Section 4(d) Rate Filing: Section 35 Version 1.0.0 to be effective 8/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5033.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1056–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Section 4(d) Rate Filing: DCP—June 30, 2016 Form of Service Agreement Change to be effective 7/30/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5042.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1057–000.
Applicants: MoGas Pipeline LLC.
Description: Compliance filing MoGas NAESB Compliance Filing to be effective 4/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5059.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1058–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Section 4(d) Rate Filing: Negotiated Rates—EDF Trading contracts 791756 & 791755 to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5069.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1059–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Section 4(d) Rate Filing: Clean Up Filing to be effective 7/30/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5083.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1060–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Section 4(d) Rate Filing: Auxiliary Installation Reimbursement Fee Change—Docket No. RP14–1200 to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5086.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1061–000.
Applicants: Dominion Transmission, Inc.
Description: Section 4(d) Rate Filing: DTI—Termination of Gathering & Products Extraction Services (CP16–1) to be effective 8/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5163.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1062–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) Rate Filing: Amendment to Neg Rate Agmt (Devon 34694–66) to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5164.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1063–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Petrohawk 41455 to Texla 46616) to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5172.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1064–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Encana 37663 to Texla 46621) to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5178.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1065–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Measurement Variance/Fuel Use Factors of Iroquois Gas Transmission System, L.P. under RP16–1065.
Filed Date: 6/30/16.
Accession Number: 20160630–5179.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1066–000.
Applicants: Rockies Express Pipeline LLC.
Description: Section 4(d) Rate Filing: Neg Rates 2016–06–30 6 Ks to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5183.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1067–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various eff 7–1–16) to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5231.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1068–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: Section 4(d) Rate Filing: Negotiated Rate Agreement Update (APS July 2016) to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5235.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1069–000.
Applicants: Texas Eastern Transmission, LP.
Description: Section 4(d) Rate Filing: EPC AUG 2016 FILING to be effective 8/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5258.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1070–000.
Applicants: Enable Gas Transmission, LLC.
Description: Section 4(d) Rate Filing: Negotiated Rate Filing—June 2016 Entergy Arkansas 8791 to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5296.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1071–000.
Applicants: White River Hub, LLC.
Description: Section 4(d) Rate Filing: Non-Conforming TSAs and Original Volume No. 2 to be effective 7/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5341.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1072–000.
Applicants: Paiute Pipeline Company.
Description: Compliance filing Adobe Fuel/Imbalance Trading to be effective 9/1/2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5346.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1073–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Section 4(d) Rate Filing: Chesapeake Energy Marketing—Negotiated Rate to be effective 7/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5000.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1074–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Section 4(d) Rate Filing: DCP—July 1, 2016 Negotiated Rate Agreement to be effective 8/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5059.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1075–000.
Applicants: ETC Tiger Pipeline, LLC.
Description: Section 4(d) Rate Filing: Revised Fuel Provision and Rates to be effective 8/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5064.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1076–000.
Applicants: WTG Hugoton, LP.
Description: Compliance filing Annual Fuel Retention Percentage Filing 2015–2016 to be effective 8/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5085.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1077–000.
Applicants: Equitrans, L.P.
Description: Section 4(d) Rate Filing: Negotiated Capacity Release Agreements—07/01/2016 to be effective 7/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5107.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1078–000.
Applicants: Texas Eastern Transmission, LP.
Description: Section 4(d) Rate Filing: Negotiated Rates—Eco-Energy Contract 8941965 to be effective 7/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5119.
Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1079–000.
Applicants: Dauphin Island Gathering Partners.
Description: Section 4(d) Rate Filing: Negotiated Rate Filing 7–1–16 to be effective 7/1/2016.
Filed Date: 7/1/16.
Accession Number: 20160701–5140.

Comments Due: 5 p.m. ET 7/13/16.

Docket Numbers: RP16–1080–000.

Applicants: Ruby Pipeline, L.L.C.

Description: Request for Waiver of Ruby Pipeline, L.L.C.

Filed Date: 6/30/16.

Accession Number: 20160630–5417.

Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1081–000.

Applicants: Eastern Shore Natural Gas Company.

Description: Section 4(d) Rate Filing: Change in FERC Gas Tariff to be effective 8/1/2016.

Filed Date: 7/1/16.

Accession Number: 20160701–5144.

Comments Due: 5 p.m. ET 7/13/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP16–549–003.

Applicants: PGPipeline LLC.

Description: Compliance filing Amended NAESB 3.0 Compliance Filing to be effective 4/1/2016.

Filed Date: 6/29/16.

Accession Number: 20160629–5212.

Comments Due: 5 p.m. ET 7/11/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 5, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16665 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–12–000]

Tennessee Gas Pipeline Company, LLC; Notice of Schedule for Environmental Review of the Southwest Louisiana Supply Project

On October 26, 2015, Tennessee Gas Pipeline Company, LLC (Tennessee) filed an application in Docket No. CP16–12–000 requesting a Certificate of Public Convenience and Necessity pursuant to section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities located in Franklin, Rapides, Richland, and Madison Parishes, Louisiana. The proposed project is known as the Southwest Louisiana Supply Project (Project), and would provide 295,000 dekatherms per day of incremental capacity to serve Mitsubishi Corporation and MMGS, Inc.

On November 9, 2015, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA—September 29, 2016
90-day Federal Authorization Decision Deadline—December 28, 2016

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Tennessee proposes to construct a 2.4-mile-long, 30-inch-diameter pipeline lateral in Madison Parish, Louisiana; a 1.4-mile-long, 30-inch-diameter pipeline lateral in Richland and Franklin Parishes, Louisiana; five meter stations to allow Tennessee to receive gas on its existing 800 Line from five interconnecting pipelines; one new compressor station in Franklin Parish, Louisiana; and replace a gas turbine engine at an existing compressor station in Rapides Parish, Louisiana.

Background

On December 9, 2015, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Southwest Louisiana Supply Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received recommendations from the U.S. Army Corps of Engineers; the State of Louisiana Department of Wildlife and Fisheries, Office of Wildlife; the State of Louisiana Department of Culture, Recreation & Tourism, Office of Cultural Development; and the Choctaw Nation of Oklahoma. The primary issues raised by the commenters are recommendations on avoiding impacts on cultural resources, wildlife, and wetlands.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (*i.e.,* CP16–12–000), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16667 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP14–112–003.
Applicants: National Fuel Gas Supply Corporation and Empire Pipeline, Inc.
Description: Joint Petition to Amend the Certificate of Public Convenience and Necessity.
Filed Date: 6/28/16.
Accession Number: 20160628–5281.
Comments Due: 5 p.m. ET 7/18/16.

Docket Numbers: CP14–96–002.
Applicants: Algonquin Gas Transmission, LLC.
Description: Abbreviated application for limited amendment of the certificate of public convenience and necessity.
Filed Date: 7/01/16.
Accession Number: 20160701–5329.
Comments Due: 5 p.m. ET 7/18/16.

Docket Number: PR16–61–000.
Applicants: SourceGas Distribution LLC.
Description: Tariff filing per 284.123(e) + (g): Statement of Operating Conditions to be effective 6/1/2016; Filing Type: 1280.
Filed Date: 6/30/2016.
Accession Number: 201606305111 *http://elibrary.ferc.gov/idmws/doc_info.asp?accession_num=20160415-5222.*
Comments Due: 5 p.m. ET 7/21/16.
284.123(g) Protests Due: 5 p.m. ET 8/29/16.

Docket Number: PR16–62–000.
Applicants: Columbia Gas of Ohio, Inc.
Description: Tariff filing per 284.123(b)(1)/.: COH SOC 6–29–2016 to be effective 6/29/2016; Filing Type: 980.
Filed Date: 7/1/16.
Accession Number: 201607015278.
Comments/Protests Due: 5 p.m. ET 7/22/16.

Docket Numbers: RP10–837–000.
Applicants: Dominion Transmission, Inc.
Description: Report Filing: DTI—Operational Gas Sales Report—2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5334.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP10–900–000.
Applicants: Dominion Transmission, Inc.
Description: Report Filing: DTI—Informational Fuel Report—2016.
Filed Date: 6/30/16.
Accession Number: 20160630–5335.
Comments Due: 5 p.m. ET 7/12/16.

Docket Numbers: RP16–1084–000.
Applicants: Dominion Transmission, Inc.
Description: Compliance filing DTI—2016 Overrun and Penalty Revenue Distribution.
Filed Date: 7/6/16.
Accession Number: 20160706–5033.
Comments Due: 5 p.m. ET 7/18/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 7, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016–16666 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–125–000]

National Fuel Gas Supply Corporation; Notice of Schedule for Environmental Review of the Line T2KNY Install, Line TNY Replacement, and Line KNY Abandonment Project

On April 4, 2016, National Fuel Gas Supply Corporation (National Fuel) filed an application in Docket No. CP16–125–000 requesting a Certificate of Public Convenience and Necessity pursuant to sections 7(b) and (c) of the Natural Gas Act to construct and abandon certain natural gas pipeline facilities. The proposed project is known as the Line T2KNY Install, Line TNY Replacement, and Line KNY Abandonment Project (Project). The Project would eliminate vintage bare steel pipeline, replacing it with modern, high strength, coated steel pipeline, therefore increasing the overall integrity and reliability of National Fuel's pipeline system.

On April 15, 2016, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA August 3, 2016
90-day Federal Authorization Decision Deadline November 1, 2016

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

National Fuel proposes to install approximately 1.2 miles of new 20-inch-diameter natural gas pipeline (Line T2KNY), replace approximately 6.7 miles of 20-inch-diameter bare steel pipeline with 7.0 miles of 24-inch-diameter coated natural gas pipeline (Line TNY), abandon approximately 14.9 miles of 20-inch-diameter bare steel natural gas pipeline (Line KNY), make modifications at two existing National Fuel meter and regulator stations (North Boston and East Eden), and make modifications at National Fuel's existing Zoar Compressor Station in Erie County, New York. The Line T2KNY Install, Line TNY Replacement, and Line KNY Abandonment Project would allow National Fuel to cure operating deficiencies on Line TNY and would provide an additional 2,600 dekatherms per day of new firm capacity which would be offered in an open season.

Background

On May 2, 2016, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Line T2KNY Install, Line TNY Replacement, and Line KNY Abandonment Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers.

To date, no comments have been received on the NOI. The New York State Department of Agriculture and Markets is a cooperating agency in the preparation of the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (*i.e.,* CP16–125), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16668 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–433; Oklahoma]

Grand River Dam Authority; Notice of Tribal Consultation Meeting

On May 6, 2016, the Grand River Dam Authority (GRDA) filed an application to amend the rule curve specified in Article 401 of the license for the Pensacola Project. The rule curve sets forth target water elevations for Grand Lake O' the Cherokees.

The Commission will hold a meeting with representatives of the tribes comprising the Inter-Tribal Council, Inc. potentially affected by GRDA's application to amend the rule curve. The meeting will be held from 9:00 a.m. to about 4:00 p.m. on Wednesday August 3, 2016, at the Miami Tribe of Oklahoma Council House, 2319 Newman Road, Miami, Oklahoma 74354.

Interested parties may attend the meeting as observers. The meeting will be transcribed by a court reporter and the transcript will be placed in the record of this proceeding.

For further information on this meeting please contact either B. Peter Yarrington at (202) 502–6129 or Linda Stewart at (202) 502–6680.

Dated: July 8, 2016

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16650 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–145–000.
Applicants: NSTAR Electric Company.
Description: Application of NSTAR Electric Company Seeking Authorization for the Acquisition of Jurisdictional Facilities under FPA Section 203.
Filed Date: 7/8/16.
Accession Number: 20160708–5159.
Comments Due: 5 p.m. ET 7/29/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1861–000.
Applicants: Tucson Electric Power Company.
Description: Report Filing: Refund Report to be effective N/A.
Filed Date: 7/8/16.
Accession Number: 20160708–5117.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER15–1862–000.
Applicants: Tucson Electric Power Company.
Description: Report Filing: Refund Report to be effective N/A.
Filed Date: 7/8/16.
Accession Number: 20160708–5119.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–1707–002.
Applicants: Upper Peninsula Power Company.
Description: Tariff Amendment: 2nd Amended Project Services Agreement to be effective 7/16/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5113.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2145–000.
Applicants: PacifiCorp.
Description: Compliance filing: PacifiCorp MBR Sales Tariff Compliance Filing per 155 FERC 61,249 to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5100.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2146–000.
Applicants: Bishop Hill Energy II LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5125.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2147–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of ISA No. 3383, Queue No. X4–004 due to Withdraw to be effective 8/6/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5127.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2148–000.
Applicants: CalEnergy, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5128.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2149–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: Amended LGIA Added Facilities Rate—Garland Project to be effective 1/3/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5129.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2150–000.
Applicants: CE Leathers Company.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5130.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2151–000.
Applicants: Cordova Energy Company LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5131.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2152–000.
Applicants: Del Ranch Company.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.

Filed Date: 7/8/16.
Accession Number: 20160708–5134.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2153–000.
Applicants: Elmore Company.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5135.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2154–000.
Applicants: Fish Lake Power LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5136.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2155–000.
Applicants: Grande Prairie Wind, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5138.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2156–000.
Applicants: Marshall Wind Energy LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5140.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2157–000.
Applicants: Pinyon Pines Wind I, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5142.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2158–000.
Applicants: Pinyon Pines Wind II, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5145.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2159–000.
Applicants: Salton Sea Power Generation Company.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5148.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2160–000.
Applicants: Salton Sea Power L.L.C.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5150.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2161–000.
Applicants: Saranac Power Partners, L.P.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5152.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2162–000.
Applicants: Solar Star California XIX, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5155.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2163–000.
Applicants: Solar Star California XX, LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5158.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2164–000.
Applicants: Topaz Solar Farms LLC.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5162.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2165–000.
Applicants: Vulcan/BN Geothermal Power Company.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5166.
Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2166–000.
Applicants: Yuma Cogeneration Associates.
Description: Compliance filing: BHE MBR Sellers Compliance Filing to be effective 6/9/2016.
Filed Date: 7/8/16.
Accession Number: 20160708–5170.
Comments Due: 5 p.m. ET 7/29/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 08, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16661 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–472–000; PF15–33–000]

Northern Natural Gas Company; Notice of Application

Take notice that on June 24, 2016, Northern Natural Gas Company (Northern), having its principal place of business at 1111 South 103rd Street, Omaha, NE 68124, filed in the above referenced docket an application pursuant to section 7(c) of the Natural Gas Act (NGA), and part 157 of the Commission's regulations requesting authorization to construct and operate compression and pipeline facilities located in Isanti, Sherburne and Rice Counties, Minnesota, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Michael T. Loeffler, Senior Director, Certificates and External Affairs for Northern, 1111 South 103rd Street, Omaha, NE 68124; by calling (402) 398–7103; by faxing (402) 398–7592; or by emailing *mike.loeffler@nngco.com.*

Specifically, Northern proposes to construct and operate 4.8 miles of 8- and 12-inch diameter branch line loop extensions in Sherburne and Isanti Counties, Minnesota. The proposed facilities will provide for incremental winter peak day firm service of 75,937 dekatherms per day serving residential, commercial, and industrial customer market growth in Northern's Market Area. Northern also proposes to install and operate an additional 15,900 horsepower compressor unit at an existing compressor station in Rice County, Minnesota. Short segments of pipeline will be removed to accommodate compressor station tie-ins. The total cost of the project is $44,068,126.

On October 9, 2015 the Commission granted Northern's request to utilize the Pre-Filing Process and assigned Docket No. PF15–33–000 to staff activities involved in the Project. Now, as of the filing of the June 24, 2016 application, the Pre-Filing Process for this Project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–472–000 as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: July 29, 2016.

Dated: July 8, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16663 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–141–000.
Applicants: Elevation Solar C LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Elevation Solar C LLC.
Filed Date: 7/7/16.
Accession Number: 20160707–5076.
Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: EC16–142–000.
Applicants: Western Antelope Blue Sky Ranch B LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Western Antelope Blue Sky Ranch B LLC.
Filed Date: 7/7/16.
Accession Number: 20160707–5082.
Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: EC16–143–000.
Applicants: GE Albany Global Holdings BV, Solar Partners I, LLC, Solar Partners II, LLC, Solar Partners VIII, LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act and Request for Waivers of GE Albany Global Holdings BV, et al.
Filed Date: 7/7/16.
Accession Number: 20160707–5169.
Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: EC16–144–000.
Applicants: GE Albany Global Holdings BV, Solar Partners I, LLC, Solar Partners II, LLC, Solar Partners VIII, LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act and Request for Waivers of GE Albany Global Holdings BV, et al.
Filed Date: 7/7/16.
Accession Number: 20160707–5173.
Comments Due: 5 p.m. ET 7/28/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–1650–007.
Applicants: Emera Maine.
Description: Compliance Filing of Emera Maine.
Filed Date: 7/5/16.
Accession Number: 20160705–5217.

Comments Due: 5 p.m. ET 7/26/16.

Docket Numbers: ER16–2142–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3220 Westar, ITC Great Plains & Mid-Kansas Interconnection Agreement to be effective 7/6/2016.

Filed Date: 7/7/16.

Accession Number: 20160707–5080.

Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: ER16–2143–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: BPA NITSA (SE Idaho Area) Rev 1 to be effective 7/1/2016.

Filed Date: 7/7/16.

Accession Number: 20160707–5114.

Comments Due: 5 p.m. ET 7/28/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 07, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16574 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Nexus Gas Transmission Project and Texas Eastern Appalachian Lease Project

	Docket No.
NEXUS Gas Transmission, LLC.	CP16–22–000
Texas Eastern Transmission, LP.	CP16–23–000
DTE Gas Company	CP16–24–000
Vector Pipeline L.P	CP16–102–000

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft environmental impact statement (EIS) for the NEXUS Gas Transmission (NGT) Project and Texas Eastern Appalachian Lease (TEAL) Project (jointly referred to as "Projects"), proposed by NEXUS Gas Transmission, LLC (NEXUS) and Texas Eastern Transmission, LP (Texas Eastern) in the above-referenced dockets. NEXUS and Texas Eastern request authorization to construct a new Greenfield pipeline and expand an existing pipeline system from the Appalachian Basin to deliver 1.5 million dekatherms per day to consuming markets in Northern Ohio, Southeastern Michigan, and Ontario, Canada. DTE Gas Company and Vector Pipeline L.P. are requesting approval to lease capacity on their systems to NEXUS.

The draft EIS assesses the potential environmental effects of the construction and operation of the Projects in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the Projects would result in some adverse environmental impacts; however, most of these impacts would be reduced to less-than-significant levels with the implementation of NEXUS's and Texas Eastern's proposed mitigation measures and the additional recommendations in the draft EIS.

Some of the route alternatives suggested during scoping would affect landowners that have not been part of the FERC's environmental scoping process, as further discussed on page 5. Therefore, by this letter we are notifying these parties of our evaluation and requesting comments about the following alternative routes presented in section 3 of the draft EIS: City of Green Route Alternative, Chippewa Lake C Route Variation, and Reserve Avenue Route Variation.

The U.S. Fish and Wildlife Service (FWS) and U.S. Environmental Protection Agency (EPA) participated as cooperating agencies in the preparation of the draft EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the National Environmental Policy Act analysis. Although the FWS and EPA provided input to the conclusions and recommendations presented in the draft EIS, the FWS and EPA will each present its own conclusions and recommendations in its respective record of decision or determination for the Projects.

The draft EIS addresses the potential environmental effects of the construction and operation of both the NGT and TEAL Projects. The NGT Project consists of about 255.9 miles of pipeline composed of the following facilities:

- 208.9 miles of new 36-inch-diameter natural gas pipeline in Ohio;
- 47 miles of new 36-inch-diameter natural gas pipeline in Michigan;
- associated equipment and facilities.

The TEAL Project would include two main components:

- 4.4 miles of new 36-inch-diameter loop pipeline in Ohio;
- 0.3 mile of new 30-inch-diameter interconnecting pipeline Ohio; and
- associated equipment and facilities.

The Projects' proposed aboveground facilities include five new compressor stations in Ohio; additional compression and related modifications to one existing compressor station in Ohio; five new metering and regulating stations in Ohio; one new metering and regulating station in Michigan; and minor modifications at existing aboveground facilities at various locations across Ohio.

The FERC staff mailed copies of the draft EIS to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries near the Projects. Paper copy versions of this draft EIS were mailed to those specifically requesting them; all others received a CD version. In addition, the draft EIS is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link.

A limited number of copies are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the draft EIS may do so. To ensure consideration of your comments on the proposal in the final EIS, it is important that the Commission receive your comments on or before August 29, 2016.

For your convenience, there are four methods you can use to submit your comments to the Commission. In all instances, please reference the Projects' docket numbers (CP16–22–000 for the NGT Project and CP16–23–000 for the TEAL Project) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the eComment

feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project.

(2) You can file your comments electronically by using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." If you are filing a comment on a particular project, please select "Comment on a Filing" as the filing type.

(3) You can file a paper copy of your comments by mailing them to the following address: Nathaniel J. Davis, Sr., Deputy Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

(4) In lieu of sending written or electronic comments, the Commission invites you to attend one of the public comment meetings its staff will conduct in the Project areas to receive comments on the draft EIS. We[1] encourage interested groups and individuals to attend and present oral comments on the draft EIS at any of the meeting locations provided on page 4.

There will *not* be a formal start of the meeting nor a formal presentation by Commission staff, but FERC staff will be available to answer your questions about the environmental review process. You may arrive *at any time* after 5:00 p.m. and we will stop taking comments at 10:00 p.m. Eastern Time Zone. The primary goal is to have your verbal environmental comments on the draft EIS documented in the public record.

Date	Location
August 10, 2016	Swanton High School, 604 North Main Street, Swanton, OH 43558, (419) 826–3045.
August 11, 2016	Tecumseh Center for the Arts, 400 North Maumee Street, Tecumseh, MI 49286, (517) 423–6617.
August 15, 2016	Quality Inn, Fremont, 3422 Port Clinton Road, Fremont, OH 43420, (419) 332–0601.
August 16, 2016	Elyria High School Performing Arts Center, 601 Middle Avenue, Elyria, OH 44035, (440) 284–5209.
August 17, 2016	Wadsworth High School—James A. Mcilvaine Performing Arts Center, 625 Broad Street, Wadsworth, OH 44281, (330) 335–1369.
August 18, 2016	Green High School, 1474 Boettler Road, Uniontown, OH 44685, (330) 896–7575.

Verbal comments will be recorded by court reporter(s) and transcriptions will be placed into the docket for the Projects and made available for public viewing on FERC's eLibrary system (see page 5 for instructions on using eLibrary). It is important to note that verbal comments hold the same weight as written or electronically submitted comments. If a significant number of people are interested in providing verbal comments, a time limit of 3 to 5 minutes may be implemented for each commenter to ensure all those wishing to comment have the opportunity to do so within the designated meeting time. Time limits will be strictly enforced if they are implemented.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (Title 18 Code of Federal Regulations Part 385.214).[2] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding that no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Route Alternatives

As indicated on page 1, some landowners are receiving this draft EIS because their property has been identified as potentially being affected by certain route alternatives recommended or being considered by FERC staff to avoid or lessen environmental impacts along NEXUS's proposed pipeline route in several locations. Refer to discussions in section 3.3.3 of the draft EIS for the City of Green Route Alternative, section 3.4.10 for the Chippewa Lake C Route Variation, and section 3.4.12 for the Reserve Avenue Route Variation. Please note that while staff has recommended the use of the last two listed alternatives, a decision whether or not to recommend the use of the City of Green Route Alternative has not been made. The Commission staff wants to ensure that all potentially affected landowners have the opportunity to participate in the environmental review process, thus staff is soliciting comments to assist with the environmental analysis of these route alternatives, which will be presented in the final EIS.

Questions?

Additional information about the Projects is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search," and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP16–22). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676; for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp* to subscribe.

Dated: July 8, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16662 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

---

[1] "We," "us," and "our" refer to the environmental staff of the FERC's Office of Energy Projects.

[2] See the previous discussion on the methods for filing comments.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–551–001]

TransCameron Pipeline, LLC; Notice of Amendment to Application for Certificate of Public Convenience and Necessity

Take notice that on June 28, 2016, TransCameron Pipeline, LLC (TransCameron), 2200 Pennsylvania Ave. NW., Suite 600 West, Washington, DC 20037, filed in the above referenced docket an amendment to the certificate application in Docket No. CP15–551–000, pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations. TransCameron proposes to (1) remove the Western Lateral from its original TransCameron Pipeline Project, (2) modify the capacity of its East Lateral without any facility changes, and (3) update East Lateral alignment and workspace for minor modifications, as was originally proposed in Cameron Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this amendment may be directed to Fory Musser, Senior Vice President, Corporate Development, Venture Global LNG, Inc., 2200 Pennsylvania Ave. NW., Suite 600 West, Washington, DC 20037.

Specifically, TransCameron originally proposed to construct, own, and operate the 23.5-mile-long East Lateral and 19.2-mile-long West Lateral, both 42-inch-diameter pipelines designed to deliver approximately 1,900,000 Dth/d of firm transportation service. However, Venture Global Calcasieu Pass—TransCameron's sole customer—optimized their LNG Terminal design and updated their natural gas transportation requirements. To comply with these changes, TransCameron now proposes to construct the 42-inch-diameter 23.5 mile-long pipeline (formerly referred to as East Lateral) that will have transmission capacity of approximately 2,125,000 Dth/d. TransCameron also requests approval of proposed initial recourse rates for transportation service and its *pro forma* FERC Gas Tariff. Amended cost of the pipeline is estimated at $198.1 million.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: July 29, 2016.

Dated: July 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–16649 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2633–025; ER10–2570–025; ER10–2717–025; ER10–3140–025; ER13–55–015.

Applicants: Birchwood Power Partners, L.P., Shady Hills Power Company, L.L.C., EFS Parlin Holdings, LLC, Inland Empire Energy Center, LLC, Homer City Generation, L.P.

Description: Notice of Non-Material Change in Status of the GE Companies.

Filed Date: 7/7/16.

Accession Number: 20160707–5217.

Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: ER12–316–001.

Applicants: NorthWestern Corporation.

Description: Report Filing: Refund Report for Refunds to Schedule 3 Customers, ER10–1138 & ER12–316 to be effective N/A.

Filed Date: 7/8/16.

Accession Number: 20160708–5046.

Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER13–2107–011; ER13–2020–011; ER13–2050–011.

Applicants: Solar Partners I, LLC, Solar Partners II, LLC, Solar Partners VIII, LLC.

Description: Notification of Change in Status of Ivanpah MBR Sellers.

Filed Date: 7/7/16.

Accession Number: 20160707–5232.

Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: ER16–1610–002.

Applicants: V3 Commodities Group, LLC.

Description: Notice of Non-Material Change in Status of V3 Commodities Group, LLC.

Filed Date: 7/7/16.

Accession Number: 20160707–5231.

Comments Due: 5 p.m. ET 7/28/16.

Docket Numbers: ER16–1706–001.

Applicants: Upper Peninsula Power Company.

Description: Tariff Amendment: Amended Common Facilities Agreement to be effective 7/16/2016.

Filed Date: 7/8/16.

Accession Number: 20160708–5067.

Comments Due: 5 p.m. ET 7/29/16.

Docket Numbers: ER16–2144–000.

Applicants: Phillips 66 Company.

Description: Section 205(d) Rate Filing: Amendment to Market-Based Rate Schedule to be effective 7/8/2016.

Filed Date: 7/7/16.

Accession Number: 20160707–5194.

Comments Due: 5 p.m. ET 7/28/16.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF16–996–000.

Applicants: SunSelect Produce (California), Inc.

Description: Form 556 of SunSelect Produce (California), Inc.

Filed Date: 6/21/16.

Accession Number: 20160621–5201.

Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 8, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16660 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the PJM Interconnection, L.L.C. (PJM):

PJM Planning Committee

July 14, 2016, 9:30 a.m.–12:00 p.m. (EST).

PJM Transmission Expansion Advisory Committee

July 14, 2016, 11:00 a.m.–3:00 p.m. (EST).

The above-referenced meetings will be held at: PJM Conference and Training Center, PJM Interconnection, 2750 Monroe Boulevard, Audubon, PA 19403.

The above-referenced meetings are open to stakeholders.

Further information may be found at *www.pjm.com.*

The discussions at the meetings described above may address matters at issue in the following proceedings:

Docket No. ER16–453, *PJM Interconnection, L.L.C. and Northeast Transmission Development, LLC*

Docket No. ER16–736, *PJM Interconnection, L.L.C.*

Docket No. ER14–972, *PJM Interconnection, L.L.C.*

Docket No. ER14–1485, *PJM Interconnection, L.L.C.*

Docket Nos. ER13–1944, *et al., PJM Interconnection, L.L.C., et al.*

Docket No. ER15–1344, *PJM Interconnection, L.L.C.*

Docket No. ER15–1387, *PJM Interconnection, L.L.C. and Potomac Electric Power Company*

Docket No. ER15–2562, *PJM Interconnection, L.L.C.*

Docket No. ER15–2563, *PJM Interconnection, L.L.C.*

Docket No. EL15–18, *Consolidated Edison Company of New York, Inc.* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–41, *Essential Power Rock Springs, LLC, et. al.* v. *PJM Interconnection, L.L.C.*

Docket No. ER15–2114, *PJM Interconnection, L.L.C. and Transource West Virginia, LLC*

Docket No. EL15–79, *TransSource, LLC* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–95, *Delaware Public Service Commission, et. al.,* v. *PJM Interconnection, L.L.C., et. al.*

Docket No. EL15–67, *Linden VFT, LLC* v. *PJM Interconnection, L.L.C.*

Docket No. EL05–121, *PJM Interconnection, L.L.C.*

Docket No. ER13–198, *PJM Interconnection, L.L.C.*

Docket No. ER16–1335, *PJM Interconnection, L.L.C.*

Docket No. ER16–1232, *PJM Interconnection, L.L.C.*

Docket No. ER16–1499, *PJM Interconnection, L.L.C.*

For more information, contact the following:

Jonathan Fernandez, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6604 *Jonathan.Fernandez@ferc.gov.*

Alina Halay, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6474, *Alina.Halay@ferc.gov.*

Dated: July 7, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–16575 Filed 7–13–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9949–04–OA]

Notification of Two Public Teleconferences of the Science Advisory Board; Environmental Economics Advisory Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces two public teleconferences of the Environmental Economics Advisory Committee (EEAC) to review its draft report regarding the EPA's proposed methodology for updating its mortality risk valuation estimates for policy analysis.

DATES: The SAB Environmental Economics Advisory Committee will conduct public teleconferences on August 4 and August 5, 2016. Each of the teleconferences will begin at 1:00 p.m. and end at 5:00 p.m. (Eastern Time).

ADDRESSES: The teleconferences will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning the public teleconferences may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; by telephone at (202) 564–2155 or via email at *armitage.thomas@epa.gov.* General information concerning the EPA SAB can be found at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB Environmental Economics Advisory Committee will hold two public teleconferences to discuss its draft report on the EPA's methodology for updating its mortality risk valuation estimates for policy analysis. The committee will provide advice to the Administrator through the chartered SAB.

The EPA's Office of Policy requested advice on proposed improvements to the Agency's methodology for estimating benefits associated with reduced risk of mortality. This methodology takes into account the amounts that individuals are willing to pay for reductions in mortality risk. The resulting values are combined into an estimate known as the value of statistical life (VSL) which is used in regulatory benefit-cost analysis. The EPA also requested that the SAB review options for accounting for changes in the VSL over time as real income grows, known as income elasticity of willingness to pay. The EPA submitted the following documents to the SAB for review: (1) *Valuing Mortality Risk for Policy: A Meta-analytic Approach,* a white paper prepared by the EPA Office of Policy to describe the Agency's interpretation and application of SAB recommendations received in July 2011 regarding updates to the EPA's estimates of mortality risk valuation; (2) *The Effect of Income on the Value of Mortality and Morbidity Risk Reductions,* a report prepared for the EPA's Office of Air and Radiation on options for updating the Agency's recommended estimate for the income elasticity of the value of statistical life; and (3) *Recommended Income Elasticity and Income Growth Estimates: Technical Memorandum,* an EPA memorandum providing supplementary information to the report. The SAB Environmental Economics Advisory Committee met on March 7–8, 2016, to receive agency briefings, hear public comments, and deliberate on responses to the EPA charge questions (81 FR 4296–4297). The committee also held teleconferences on June 16 and June 17, 2016 to discuss its draft report with responses to the charge questions (81 FR 30535–30536). The purpose of the teleconferences described in this notice is to continue the discussion of the committee's draft report. The two committee teleconferences will be conducted as one complete meeting beginning on August 4, 2016 and continuing on August 5, 2016, if needed to complete agenda items. Additional information about this SAB advisory activity can be found at the following URL: *http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Valuing%20fatal%20risk%20for%20policy?OpenDocument.*

Technical Contacts: Any technical questions concerning the EPA documents reviewed by the SAB should be directed to Dr. Nathalie Simon in the EPA's National Center for Environmental Economics, by telephone at (202) 566–2347 or by email at *simon.nathalie@epa.gov.*

Availability of Meeting Materials: Prior to the meeting, the teleconference agenda, draft committee report, and other materials will be available on the SAB Web site at *http://www.epa.gov/sab.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Interested members of the public may submit relevant information on the topic of this advisory activity, and/or the group conducting the activity, for the SAB to consider during the advisory process. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB committees and panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly. *Oral Statements:* In general, individuals or groups requesting an oral presentation at the teleconference will be limited to three minutes. Interested parties wishing to provide comments should contact Dr. Armitage, DFO, in writing (preferably via email) at the contact information noted above by July 28, 2016, to be placed on the list of public speakers for the meeting. *Written Statements:* Written statements will be accepted throughout the advisory process; however, for timely consideration by committee members, statements should be supplied to the DFO (preferably via email) at the contact information noted above by July 28, 2016. It is the SAB Staff Office general policy to post written comments on the Web page for advisory meetings. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Armitage at the contact information provided above. To request accommodation of a disability, please contact Dr. Armitage preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: July 5, 2016.

Thomas H. Brennan,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2016–16710 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0338; FRL–9948–03]

Alpha-chlorohydrin and Hydrogen Cyanamide Registration Review Interim Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decisions for the pesticides alpha-chlorohydrin (case 4120) and hydrogen cyanamide (case 7005). Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the table in Unit II., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the table in Unit II.

FOR FURTHER INFORMATION CONTACT:

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0338 is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the agency taking?

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's interim registration review decisions for the pesticides shown in the following table.

TABLE—INTERIM REGISTRATION REVIEW DECISIONS

Registration review case name and No.	Pesticide docket ID No.	Chemical review manager, telephone number, email address
Alpha-chlorohydrin, Case 4120	EPA–HQ–OPP–2015–0726	Matthew Manupella, (703) 347–0411, *manupella.matthew@epa.gov.*
Hydrogen cyanamide, Case 7005	EPA–HQ–OPP–2007–1014	Dana L. Friedman, (703) 347–8827, *friedman.dana@epa.gov.*

Alpha-chlorohydrin. The registration review docket for alpha-chlorohydrin opened in December 2015. For alpha-chlorohydrin, the Agency expedited the registration review and opened the docket with the proposed interim decision and supporting documents. The only registered use for alpha-chlorohydrin is as a tamper-proof bait station/bait application delivery system for elimination of Norway rats. Alpha-chlorohydrin is approved for use in and around commercial/industrial facilities and sanitary sewers. The label prohibits the use of the product in any facility where children may be present, and no outdoor uses are permitted. Exposure to pollinators is unlikely because alpha-chlorohydrin is deployed in a bait station. Therefore, pollinator data will not be required, nor will exposure to pollinators be assessed. The Agency has made the following interim decision: (1) No additional data are required at this time; (2) no changes to the affected registrations or their labeling are needed at this time; and (3) EPA does not expect alpha-chlorohydrin to have direct or indirect adverse effects to non-listed, and listed species or to adversely modify any designated critical habitat for such species, and is making a "no effect" determination under the Endangered Species Act for all listed species and designated critical habitat for such species. At this time, EPA is making no human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of alpha-chlorohydrin. EPA's registration review decision for alpha-chlorohydrin will depend upon the result of an EDSP Federal Food, Drug and Cosmetic Act (FFDCA) section 408(p) determination.

Hydrogen cyanamide. Hydrogen cyanamide is a plant growth regulator used to promote uniform bud break in orchard fruit trees and vines; there are no residential uses. It is the only registered plant growth regulator available to induce uniform bud break in United States fruit production, and there are significant economic benefits associated with its use in areas where the critical number of chilling hours needed for bud break do not occur or are not consistent. The Agency conducted a comprehensive human health risk assessment and determined that there are potential risks of concern for occupational handlers, as well as spray drift concerns for bystanders. The occupational risks can be mitigated through modifications to the cyanamide label, and spray drift concerns are addressed by a distance restriction for bystanders. The Agency also conducted an ecological risk assessment and determined that there are potential risks of concern for terrestrial animals, but current use practices and label mitigation address many of these concerns. In this Interim Registration Review Decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of cyanamide or risks to pollinators, nor is it making a complete endangered species finding. The Agency's final registration review decision is dependent upon the assessment of risks to threatened and endangered species, and to pollinators, and of potential endocrine disruptor risk.

Pursuant to 40 CFR 155.57, a registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. EPA has considered alpha-chlorohydrin and hydrogen cyanamide in light of the FIFRA standard for registration. The Interim Decision documents in the docket for these pesticides describe the Agency's rationale for issuing the interim decisions.

In addition to the interim registration review decision documents, the registration review dockets for alpha-chlorohydrin and hydrogen cyanamide include other relevant documents related to the registration review of these pesticides. The proposed interim registration review decisions were posted to the docket and the public was invited to submit any comments or new information. EPA addressed the comments or information received during the comment period in the discussions for alpha-chlorohydrin and hydrogen cyanamide. During the 60–day comment period, the public comments received for both pesticides did not affect the Agency's interim decisions. Pursuant to 40 CFR 155.58(c), the registration review case dockets for alpha-chlorohydrin and hydrogen cyanamide will remain open until all actions required in the interim decision have been completed.

Background on the registration review program is provided at: *http://www.epa.gov/oppsrrd1/registration_review.* Links to earlier documents related to the registration review of this pesticide are provided at: *http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 6, 2016.

Michael Goodis,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–16708 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0774; FRL–9948–29]

Registration Review Proposed Decisions for Sulfonylureas and Certain Other Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed interim registration review and opens a 60-day public comment period on the proposed interim decisions. It also opens the docket for Bacillus thuringiensis. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the tables in Unit II, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the tables in Unit II.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the tables in Unit II.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at

http://www.epa.gov/dockets/comments.html.

II. What action is the agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for the pesticides shown in the following tables, and opens a 60-day public comment period on the proposed interim decisions.

A single Proposed Interim Registration Review Decision document covering the 22 sulfonylurea chemicals listed in Table 1 is being made available for public review and comment. Public comments submitted to any of the 22 sulfonylurea dockets will be considered for the sulfonylureas as a group, as appropriate.

TABLE 1—REGISTRATION REVIEW PROPOSED INTERIM DECISION FOR SULFONYLUREAS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Bensulfuron-methyl 7216	EPA–HQ–OPP–2011–0663	Moana Appleyard, *appleyard.moana@epa.gov*, (703) 308–8175.
Chlorimuron-ethyl 7403	EPA–HQ–OPP–2010–0478	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553.
Chlorsulfuron 0631	EPA–HQ–OPP–2012–0878	Miguel Zavala, *zavala.miguel@epa.gov*, (703) 347–0504.
Flazasulfuron 7271	EPA–HQ–OPP–2011–0994	Ricardo Jones, *jones.ricardo@epa.gov*, (703) 347–0493
Foramsulfuron 7252	EPA–HQ–OPP–2012–0387	Jose Gayoso, *gayoso.jose@epa.gov*, (703) 347–8652.
Halosulfuron-methyl 7233	EPA–HQ–OPP–2011–0745	Brittany Pruitt, *pruitt.brittany@epa.gov*, (703) 347–0289.
Imazosulfuron 7281	EPA–HQ–OPP–2015–0625	Caitlin Newcamp, *newcamp.caitlin@epa.gov*, (703) 347–0325.
Iodosulfuron-methyl-sodium 7253	EPA–HQ–OPP–2012–0717	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553.
Mesosulfuron-methyl 7263	EPA–HQ–OPP–2012–0833	Maria Piansay, *piansay.maria@epa.gov*, (703) 308–8063.
Metsulfuron-methyl 7205	EPA–HQ–OPP–2011–0375	Brian Kettl, *kettl.brian@epa.gov*, (703) 347–0535.
Nicosulfuron 7227	EPA–HQ–OPP–2012–0372	Nathan Sell, *sell.nathan@epa.gov*, (703) 347–8020.
Orthosulfamuron 7270	EPA–HQ–OPP–2011–0438	Khue Nguyen, *nguyen.khue@epa.gov*, (703) 347–0248.
Primisulfuron-methyl 7220	EPA–HQ–OPP–2011–0844	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201.
Prosulfuron 7235	EPA–HQ–OPP–2011–1010	Wilhelmena Livingston, *livingston.wilhelmena@epa.gov*, (703) 308–8025.
Rimsulfuron 7218	EPA–HQ–OPP–2012–0178	Jose Gayoso, *gayoso.jose@epa.gov*, (703) 347–8652.
Sulfometuron-methyl 3136	EPA–HQ–OPP–2012–0433	Caitlin Newcamp, *newcamp.caitlin@epa.gov*, (703) 347–0325.
Sulfosulfuron 7247	EPA–HQ–OPP–2011–0434	Nicole Zinn, *zinn.nicole@epa.gov*, (703) 308–7076.
Thifensulfuron-methyl 7206	EPA–HQ–OPP–2011–0171	Steven Snyderman, *snyderman.steven@epa.gov*, (703) 347–0249.
Triasulfuron 7221	EPA–HQ–OPP–2012–0115	Margaret Hathaway, *hathaway.margaret@epa.gov*, (703) 305–5076.
Tribenuron-methyl 7217	EPA–HQ–OPP–2010–0626	Linsey Walsh, *walsh.linsey@epa.gov*, (703) 374–8030.
Trifloxysulfuron-Sodium 7028	EPA–HQ–OPP–2013–0409	Nicole Zinn, *zinn.nicole@epa.gov*, (703) 308–7076.
Triflusulfuron-methyl 7236	EPA–HQ–OPP–2012–0605	Susan Bartow, *bartow.susan@epa.gov*, (703) 603–0065.

The chemicals included below in Table 2 are not sulfonylureas chemicals and have individual Proposed Interim Registration Review Decision documents.

TABLE 2—REGISTRATION REVIEW PROPOSED INTERIM DECISION—ADDITIONAL CHEMICALS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Antimycin A 4121	EPA–HQ–OPP–2015–0480	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201.
Bacillus thuringiensis 6503	EPA–HQ–OPP–2016–0200	Jennifer Wingeart, *wingeart.jennifer@epa.gov*, (703) 347–0100.
Flufenacet 7245	EPA–HQ–OPP–2010–0863	Brian Kettl, *kettl.brian@epa.gov*, (703) 347–0535.
Flurprimidol 7000	EPA–HQ–OPP–2009–0630	Kelly Ballard, *ballard.kelly@epa.gov*, (703) 305–8126.
Fosamine Ammonium 2355	EPA–HQ–OPP–2010–0215	James Parker, *parker.james@epa.gov*, (703) 306–0469.
Glufosinate Case 7224	EPA–HQ–OPP–2008–0190	Marquea D. King, *king.marquea@epa.gov*, (703) 305–7432.
Lithium Hypochlorite 3084	EPA–HQ–OPP–2013–0606	Sandra O'Neill, *oneill.sandra@epa.gov*, (703) 347 0141.
Tebufenozide 7416	EPA–HQ–2008–0824	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201.

The registration review docket for a pesticide includes earlier documents related to the registration review case, except for *Bacillus thuringiensis,* whose docket is now opening. For example, the review opened with a Summary Document, containing a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the tables in Unit II, as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. These proposed interim registration review decisions are supported by the rationales included in those documents.

Following public comment, the Agency will issue interim or final registration review decisions for the pesticides listed in the tables in Unit II.

The registration review program is being conducted under congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public. Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) required EPA to establish by regulation procedures for reviewing pesticide registrations, originally with a goal of reviewing each pesticide's registration every 15 years to ensure that a pesticide continues to meet the FIFRA standard for registration. The Agency's final rule to implement this program was issued in August 2006 and became effective in October 2006, and appears at 40 CFR part 155, subpart C. The Pesticide Registration Improvement Act of 2003 (PRIA) was amended and extended in September 2007. FIFRA, as amended by PRIA in 2007, requires EPA to complete registration review decisions by October 1, 2022, for all pesticides registered as of October 1, 2007.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the tables in Unit II. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a "Response to Comments Memorandum" in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www2.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 6, 2016.

Michael Goodis,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–16709 Filed 7–13–16; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

[3046–007]

Agency Information Collection Activities; Notice of Submission for OMB Review, Final Comment Request: Revision of the Employer Information Report (EEO–1)

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Equal Employment Opportunity Commission (EEOC or Commission) announces that it is submitting to the Office of Management and Budget (OMB) a request for a three-year PRA approval of a revised Employer Information Report (EEO–1) data collection. Employers have submitted the EEO–1 report for over fifty years. The Commission is responsible for PRA compliance for the EEO–1, although it is a joint data collection to meet the statistical needs of both the EEOC and the U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP). This PRA submission has two components. Component 1 describes the data now collected by the currently approved EEO–1, which is data about employees' ethnicity, race, and sex by job category (demographic data). Component 2 describes the W–2 (Box 1) and hours-worked data that will be added to the EEO–1 with OMB's approval under this PRA request (pay data). EEO–1 respondents must comply with the 2016 filing requirement for the currently approved EEO–1.

DATES: Submit comments on or before August 15, 2016.

ADDRESSES: Comments on this notice must be submitted to Joseph B. Nye, Policy Analyst, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, email *oira_submission@omb.eop.gov.* Commenters are also encouraged to send comments to the EEOC online at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions on the Web site for submitting comments. In addition, the EEOC's Executive Secretariat will accept comments in hard copy by delivery by COB on August 15, 2016. Hard copy comments should be sent to Bernadette Wilson, Acting Executive Officer, EEOC, 131 M Street NE., Washington, DC 20507. Finally, the Executive Secretariat will accept comments totaling six or fewer pages by facsimile ("fax") machine before the same deadline at (202) 663–4114. (This is not a toll-free number.) Receipt of fax transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll-free telephone numbers.) The EEOC will post online at *http://www.regulations.gov* all comments submitted via this Web site, in hard copy, or by fax to the Executive Secretariat. These comments will be posted without change, including any personal information you provide. However, the EEOC reserves the right to refrain from posting libelous or otherwise inappropriate comments including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; that contain hate speech directed at race, color, sex, national origin, age, religion, disability, or genetic information; or that promote or endorse services or products. All comments received, including any personal information provided, also will be available for public inspection during normal business hours by appointment only at the EEOC Headquarters' Library, 131 M Street NE., Washington, DC 20507. Upon request, individuals who require assistance viewing comments will be provided appropriate aids such as readers or print magnifiers. To schedule an appointment, contact EEOC Library staff at (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll-free numbers.)

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, Equal Employment Opportunity Commission, 131 M Street NE., Room 4SW30F, Washington, DC 20507; (202) 663–4949 (voice) or (202) 663–7063 (TTY). Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or (202) 663–4494 (TTY).

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. The EEOC's Legal Authority To Propose This EEO–1 Report
  A. Title VII of the Civil Rights Act of 1964

B. The Paperwork Reduction Act of 1995
III. Revisions to the EEO–1 Report Are Necessary for the Enforcement of Title VII, the EPA, and Executive Order 11246
IV. Who Will Report Pay Data on the Revised EEO–1
A. Employers That Currently File the EEO–1
B. 60-Day Notice: Which Employers Would File Pay Data
C. Public Comments
D. 30-Day Notice: Employers With 100 or More Employees Will File Components 1 & 2
V. When To File: Filing Deadline and Workforce Snapshot Period
A. 60-Day Notice
B. Public Comments
C. 30-Day Notice
1. Deadline for Filing the EEO–1
2. "Workforce Snapshot" Period
VI. What Pay Data To Report: Measure of Pay for the EEO–1
A. 60-Day Notice: Options for Measuring Pay
B. Public Comments
1. Supporting the Use of W–2 Income
2. Opposing the Use of W–2 Income
C. 30-Day Notice: W–2 (Box 1) Income Is the Measure of Pay
1. W–2 Income and Employee Choice
2. Supplemental Income Is Important and May Be Linked to Discrimination
3. Bridging HRIS and Payroll
VII. What Data To Report: Hours Worked
A. 60-Day Notice
B. Public Comments
C. 30-Day Notice
1. The Importance of Collecting Hours Worked
2. Defining "Hours Worked"
3. Reporting Hours Worked for Nonexempt Employees
4. Reporting Hours Worked for Exempt Employees
VIII. How To Report Data in Component 2: Pay Bands and Job Categories
A. 60-Day Notice
B. Public Comments
C. 30-Day Notice
IX. How the EEOC Will Use W–2 and Hours-Worked Data
A. 60-Day Notice
B. Public Comments
C. 30-Day Notice
1. Early Assessment of Charges of Discrimination
2. EEOC Publications Analyzing Aggregate EEO–1 Data
3. EEOC Training on the Pay Data Collection
X. Confidentiality of EEO–1 Data
A. 60-Day Notice
B. Public Comments
C. 30-Day Notice
1. Legal Confidentiality
a. EEOC
b. OFCCP
2. Data Protection and Security
XI. Paperwork Reduction Act Burden Estimates
A. Background
B. 60-Day Notice
C. 30-Day Notice
1. Annual Burden Hours
2. Hourly Wage Rates
XII. Formal Paperwork Reduction Act Statement
A. Overview of Information Collection
1. 2016 Overview of Information Collection—Component 1
2. 2017 and 2018 Overview of Information Collection—Components 1 and 2
a. Component 1 (Demographic and Job Category Data)
b. Components 1 and 2 (Demographic and Job Category Data Plus W–2 and Hours Worked Data)
B. 30-Day Notice PRA Burden Statement

I. Background

This final proposal to supplement the longstanding EEO–1 employer information report (currently approved by OMB under Control Number 3046–0007) is intended to support the EEOC's pay discrimination investigations by collecting employer- and gender-, race-, and ethnicity-specific pay data to identify pay disparities that may result from discriminatory practices or policies. This Notice provides stakeholders with their second opportunity to comment on this proposal.

The EEOC published the first notice of this proposed revision in the **Federal Register** on February 1, 2016, for a 60-day comment period (the "60-Day Notice").[1] It announced which employers would be required to file pay data, what data would be collected, when the due date would be, how the data would be analyzed, and how the proposed collection and analysis would protect confidentiality and privacy. As required, the 60-Day Notice estimated the cost to employers of completing the current EEO–1 (Component 1) and the proposed revision of the EEO–1 (Components 1 and 2).

The EEOC received 322 timely public comments in response to the 60-Day Notice. The comments were submitted by individual members of the public, employers, employer associations, Members of Congress, civil rights groups, women's organizations, labor unions, industry groups, law firms, and human resources organizations. Over 120 of the 322 comments were part of mass mail campaigns mostly supporting the proposal, although one mass mail campaign opposed the proposal. The mass mail campaigns included submissions from organizations that collected up to thousands of signatures from their members or supporters.

The Commission also held a public hearing on March 16, 2016, and heard from 15 witnesses representing a range of stakeholders including employers, employees, and academics. The Commission reviewed their detailed written submissions, heard them discuss their different perspectives on the proposal, and asked them questions.[2]

Pursuant to the required procedures under the PRA, the Commission now publishes its final proposal to supplement the EEO–1 for a second round of public comments, to last 30 days (hence the "30-Day Notice"). The EEOC also is formally submitting the proposed EEO–1 revisions to OMB for consideration and decision.

This 30-Day Notice summarizes the 60-Day Notice, describes the public comments, and explains the Commission's decisions. In making these decisions, the Commission took into account all of the hearing testimony and public comments. The Commission also assessed government data regarding components of compensation in United States workplaces, relevant academic literature on compensation practices and on discrimination, and the conclusions of two studies commissioned by the EEOC to examine how and whether to implement a pay data collection.[3] This 30-Day Notice sets forth the EEOC's conclusions about the ways the proposed pay data collection will be used to enhance and increase the efficiency of enforcement efforts while facilitating employer self-evaluation and voluntary compliance.

II. The EEOC's Legal Authority To Propose This EEO–1 Report

In written comments in response to the 60-Day Notice, several interested parties questioned whether the EEOC has legal authority to collect pay data and whether the agency should have conducted a formal rulemaking to impose a pay data reporting requirement. As explained in more detail below, the EEOC has the legal authority to collect pay data under Title VII of the Civil Rights Act of 1964, as amended (Title VII),[4] without conducting a formal rulemaking because the EEOC is responsible for enforcing federal laws that prohibit wage discrimination on the basis of sex, race and national origin, and Title VII grants the EEOC broad authority to collect data from employers regarding compliance with federal anti-discrimination laws. The EEOC has exercised this statutory authority by implementing a regulation to establish the EEO–1 reporting requirement, and now administers the EEO–1 report pursuant to the PRA.

---

[1] 81 FR 5113 (Feb. 1, 2016).

[2] The press release on the hearing is available at EEOC, *EEOC Hears Wide Range of Views at Public Hearing on Proposed Changes to EEO–1 Form* (Mar. 16, 2016), *https://www.eeoc.gov/eeoc/newsroom/release/3-16-16.cfm*. The statements and biographies of the witnesses are available at EEOC, *Hearing of March 16, 2016—Public Input into the Proposed Revisions to the EEO–1 Report, http://www.eeoc.gov/eeoc/meetings/3-16-16/*.

[3] The first EEOC-commissioned study, resulting in a 2012 report from the National Research Council, National Academy of Sciences (NAS Report), outlined the potential value for EEOC enforcement of collecting pay data from employers by sex, race, and national origin through a report such as the EEO–1. National Research Council, 2012. *Collecting Compensation Data from Employers*. Washington, DC: National Academies Press, *http://www.nap.edu/read/13496/chapter/1#ii*. The second study, reported by an EEOC contractor in 2015, provided detailed analysis of different approaches to implementing the report and included assessments of different statistical analyses for employer data. Sage Computing, *EEOC Pay Pilot Study* (September, 2015), *http://www.eeoc.gov/employers/eeo1survey/pay-pilot-study.pdf*.

A. Title VII of the Civil Rights Act of 1964

The EEOC is responsible for enforcing Title VII, which prohibits all employment discrimination, including pay discrimination, based on race, color, religion, national origin, or sex.[5] The EEOC also enforces other federal laws prohibiting employment discrimination, including the Equal Pay Act of 1963 (EPA), which prohibits certain gender-based pay discrimination.[6]

The EEOC's authority to promulgate the EEO–1 report is found in section 709(c) of Title VII, which requires employers covered by Title VII to make and keep records relevant to whether unlawful employment practices have been or are being committed, to preserve such records, and to produce reports as the Commission prescribes by regulation or order, after public hearing, "as reasonable, necessary, or appropriate for the enforcement of this subchapter or the regulations . . . thereunder."[7] The Commission prescribes the EEO–1 report by regulation at 29 CFR part 1602, subpart B, which requires private employers with 100 or more employees to "file [annually] with the Commission or its delegate executed copies of [the] . . . EEO–1 [report] in conformity with the directions set forth in the form and accompanying instructions." The EEOC administers the EEO–1 jointly with OFCCP, which enforces the employment discrimination prohibitions of Executive Order 11246, as amended, for federal contractors and subcontractors (contractors), including specific provisions regarding pay discrimination and transparency.[8] OFCCP's regulations require contractors to submit "complete and accurate reports on Standard Form 100 (EEO–1) . . . or such form as may hereafter be promulgated in its place."[9] The Joint Reporting Committee, composed of the EEOC and OFCCP and located at the EEOC, administers the EEO–1 as a single data collection to meet the statistical needs of both agencies while avoiding duplication.

B. The Paperwork Reduction Act of 1995

Since 1995, the EEO–1 report also has been governed by the Paperwork Reduction Act of 1995 (PRA), which provides standards for federal data collections and requires periodic Office of Management and Budget (OMB) review and renewal.[10] The EEOC is responsible for maintaining PRA approval of the EEO–1.

The EEOC, like other federal agencies subject to the PRA, generally follows a multi-step process for maintaining OMB approval of an information collection, which culminates in OMB deciding if the proposed collection "strikes a balance between collecting information necessary to fulfill [the agency's] statutory mission[ ] and guarding against unnecessary or duplicative information that imposes unjustified costs on the American public."[11] The first step is for the agency to publish a proposed information collection for a 60-day public comment period, which ran from February 1 to April 1, 2016 for this EEO–1 revision.[12] Then, in light of the public comments and its statutory mission, the agency formulates a final data collection, which it publishes in the **Federal Register** and submits to OMB for approval, subject to a 30-day public comment period.[13] The current document, which has been approved by a majority of the Commission, is the EEOC's 30-Day Notice for the revised EEO–1.

The EEOC has consistently used the PRA renewal process to change the EEO–1. Most recently, in 2006, the PRA process was used to significantly revise the EEO–1 by adding a new race category, requiring employers to ask employees to self-identify by race and ethnicity, and requiring employers to ask about ethnicity (Hispanic or Latino) in a separate question.[14] The 2006 EEO–1 revision also added a new job category.[15]

III. Revisions to the EEO–1 Report Are Necessary for the Enforcement of Title VII, the EPA, and Executive Order 11246

Some public comments opposing the EEOC's proposal in the 60-Day Notice questioned whether there are still pay disparities that are caused by discrimination linked to gender, race, or ethnicity and, accordingly, whether there is actually a need for more effective enforcement of the prohibitions on pay discrimination in Title VII, the EPA, and E.O. 11246.

Based on federal data and a robust body of research, the Commission concludes that: (1) Persistent pay gaps continue to exist in the U.S. workforce correlated with sex, race, and ethnicity; (2) workplace discrimination is an important contributing factor to these pay disparities; and (3) implementing the proposed EEO–1 pay data collection will improve the EEOC's ability to efficiently and effectively structure its investigation of pay discrimination charges.

First, persistent pay gaps exist in the U.S. workforce correlated with sex, race, and ethnicity. As of 2014, for women of all races and ethnicities, the median annual pay for a woman who held a full-time, year-round job was $39,621, while the median annual pay for a man who held a full-time, year-round job was $50,383.[16]

---

[4] 42 U.S.C. 2000e, *et seq.*

[5] *Id.*

[6] 29 U.S.C. 206(d).

[7] 42 U.S.C. 2000e–8(c).

[8] E.O. 11246, as amended, 30 FR 12319, 41 CFR 60–1.7(a). Executive Order 13665 amends E.O. 11246 to promote pay transparency for federal contractors, protect employees and job applicants, and make it possible for employees and job applicants to share information about their pay without fear of discrimination. E.O. 13665, 79 FR 20749, available at: *https://www.gpo.gov/fdsys/pkg/DCPD-201400250/pdf/DCPD-201400250.pdf.* OFCCP's recently adopted final rule on sex discrimination (OFCCP Rule on Discrimination on the Basis of Sex) addresses a number of sex-based barriers to equal employment and fair pay. The rule requires contractors to provide equal opportunities "without regard to sex." 41 CFR part 60–20. *See also* 81 FR 39108, 39125–39129 (June 15, 2016).

[9] 41 CFR 60–1.7(a).

[10] According to the OMB, "collection of information" may include: (1) Requests for information to be sent to the government, such as forms (*e.g.,* the IRS 1040), written reports (*e.g.,* grantee performance reports), and surveys (*e.g.,* the Census); (2) recordkeeping requirements (*e.g.,* OSHA requirements that employers maintain records of workplace accidents); and third-party or public disclosures (*e.g.,* nutrition labeling requirements for food).

Office of Information and Regulatory Affairs, OMB, Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies, *Information Collection under the Paperwork Reduction Act* (Apr. 7, 2010), *https://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/PRAPrimer_04072010.pdf; See also* 5 CFR 1320.3(c).

[11] *Id.*

[12] 81 FR 5113 (Feb. 1, 2016).

[13] 44 U.S.C. 3507(a)(1).

[14] EEOC, *EEOC Implements Finals Revisions to EEO–1 Report* (Jan. 27, 2006), *https://www.eeoc.gov/eeoc/newsroom/release/archive/1-27-06.html; See also* 70 FR 71294 (Nov. 28, 2005); OMB approved these changes on January 25, 2006, Office of Information and Regulatory Affairs, *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200511-3046-001#.*

[15] *Id.*

[16] Carmen DeNavas-Walt and Bernadette Proctor, U.S. Census Bureau, *Income and Poverty in the*

Continued

African American and Hispanic or Latina women nationwide now experience the largest pay disparities. As of 2014, African American women were paid almost 40% less than white, non-Hispanic, men and approximately 20% less than white, non-Hispanic women.[17] At a national level, African American women were paid 18% less than African American men.[18]

Similarly, Latina women were paid approximately 44% less than white, non-Hispanic men, and 27% less than white, non-Hispanic, women in 2014.[19] The result of the wage gap is that the average Hispanic or Latina woman would be paid approximately $1,007,000 less than the average white, non-Hispanic, male over a 40-year period.[20]

A similar pattern exists for Native Hawaiian and Pacific Islander women and Native American women who were paid approximately 38% and 41% less than white, non-Hispanic men, respectively.[21] Asian American women were paid 10% less than white, non-Hispanic men.[22]

Wage disparities also exist for men of color. In 2014, African American men who worked full time in wage and salary jobs had median weekly earnings of $680, which represented approximately 76% of white men's median weekly earnings ($897).[23] Hispanic men earned $616, or approximately 69%, of white men's median weekly earnings.[24]

Employment discrimination may play both direct and indirect roles in creating these pay disparities. Economists Francine Blau and Lawrence Khan found that 64.6% of the wage gap between men and women can be explained by three factors: Experience (14.1%), industry (17.6%), and occupation (32.9%).[25] Men are more likely to work in blue collar jobs that are higher paying, including construction, production, or transportation occupations, whereas women are more concentrated in lower paying professions, such as office and administrative support positions.[26] Most of the remaining 35.4% of the gender gap cannot be explained by differences in education, experience, industry, or occupation.[27] Blau and Khan argue that discrimination—intentional or unintentional, systematic or at the individual level—plays a role in explaining the gap.[28]

Gender bias may become more obvious when occupations have a greater proportion of women. One study found that, in an occupation dominated by men, pay declines when women enter that occupation in large numbers, even after controlling for factors such as education and work experience.[29] The opposite effect occurred when a larger proportion of men entered a profession previously dominated by women, *i.e.*, pay increased.[30]

One way that gender discrimination may influence pay is through implicit or unconscious bias during hiring, promotion decisions, or job assignments.[31] A study by McKinsey & Company found that women are almost three times more likely than men to have missed out on an assignment, promotion, or increase in wages because of their gender.[32] Another study shows that women who engage in pay negotiations are more likely than men to face backlash due to gender stereotypes.[33]

Similar to gender discrimination, racial discrimination may influence pay through implicit or unconscious bias. A series of studies by MIT Sloan found racial bias in salary negotiations even after controlling for the applicants' objective qualifications.[34] Research by

---

United States: 2014, Current Population, 6 (2015), Table 1: Income and Earnings Summary Measures by Selected Characteristics: 2013 and 2014, *https://www.census.gov/content/dam/Census/library/publications/2015/demo/p60-252.pdf.*

[17] Joan Farrelly-Harrigan, U.S. Dep't. of Labor, Women's Bureau, *Black Women in the Labor Force* (Feb. 2016), *https://www.dol.gov/wb/media/Black_Women_in_the_Labor_Force.pdf* (reporting that African American women's median annual earnings in 2014 was $33,533, $41,822 for white, non-Hispanic women, and $55,470 for white, non-Hispanic men).

[18] *Id.*

[19] Michelle Vaca, U.S. Dep't. of Labor Blog, *Celebrating Hispanic Women in the Labor Force* (Oct. 6, 2015), *http://blog.dol.gov/2015/10/06/celebrating-hispanic-women-in-the-labor-force/* (reporting that the 2013 median annual earnings for Latinas was $30,209).

[20] Joint Economic Committee, United States Congress, *Gender Pay Inequality,* 3 (April 2016) *http://www.jec.senate.gov/public/_cache/files/0779dc2f-4a4e-4386-b847-9ae919735acc/gender-pay-inequality----us-congress-joint-economic-committee.pdf.*

[21] American Association of University Women, *The Simple Truth About the Gender Pay Gap,* 10 (Spring 2016), *http://www.aauw.org/files/2016/02/SimpleTruth_Spring2016.pdf* (reporting that the median annual earnings for Native Hawaiian and Pacific Islander women was $32,893 and $31,191 for Native American women).

[22] *Id.* (reporting that Asian American women's median earnings in 2014 was $47,776).

[23] U.S. Dept. of Labor, Bureau of Labor Statistics, *Women in the labor force; a databook,* BLS Reports, 60–61 (Dec. 2015), Table 16: Median usual weekly earnings of full-time wage and salary workers, in current dollars, by race, Hispanic, or Latino ethnicity, and gender, 1979–2014 annual averages, *http://www.bls.gov/opub/reports/womens-databook/archive/women-in-the-labor-force-a-databook-2015.pdf.*

[24] *Id.*

[25] Francine Blau and Lawrence Kahn, *The Gender Wage Gap: Extent, Trends, and Explanations,* Institute for the Study of Labor, 73 (Jan. 2016), Table 4: Decomposition of Gender Wage Gap, 1980 and 2010 (PSID), *http://ftp.iza.org/dp9656.pdf* (the authors reported that the gender wage gap for purposes of the study was approximately 79 cents on the dollar in 2010).

[26] DeNavas-Walt and Proctor, *supra* note 16 at 5; *see also* PayScale, *Inside the Gender Pay Gap,* (2016), *http://www.payscale.com/data-packages/gender-pay-gap* (reporting that across the United States women are more likely to be overrepresented in lower paying jobs (jobs that pay less than $60,000 per year) and underrepresented in higher paying jobs compared to men. In addition, female pay levels off at $49,000 between the ages of 35–40 whereas men's pay levels off at $75,000 for the ages of 50–55).

[27] Blau & Kahn, *supra* note 25 at 73, Table 4.

[28] *Id.* A smaller portion of the gap (approximately 5%) can be attributed to geographic region (0.3%) and race (4.3%). The authors do not provide an explanation about why only 4% of the pay gap is attributed to race despite federal data suggesting that the wage gap between and within minorities is much larger. However, women's gains in education helped to narrow the gender wage gap by almost 6% as women now exceed men in educational attainment.

[29] Asaf Levanon, Paula England, Paul Allison, *Occupational Feminization and Pay: Assessing Casual Dynamics Using 1950–2000 U.S. Census Data,* Social Forces 88(2) (Dec. 2009), *http://statisticalhorizons.com/wp-content/uploads/2012/01/88.2.levanon.pdf.*

[30] Claire Cain Miller, *As Women Take Over a Male Dominated Field, the Pay Drops,* NY Times (Mar. 18, 2016), *http://www.nytimes.com/2016/03/20/upshot/as-women-take-over-a-male-dominated-field-the-pay-drops.html?_r=0* (reporting that when more women became designers, for example, wages fell by 34 percentage points. When male computer programmers outnumbered women computer programmers, the job began to pay more and earned more prestige).

[31] Nancy Lockwood, *The Glass Ceiling: Domestic and International Perspectives,* 3 Society for Human Resource Management Quarterly 2004, *https://www.shrm.org/Research/Articles/Articles/Documents/040329Quaterly.pdf* (reporting that signs of the glass ceiling in the workplace can be based on gender-based barriers that may be invisible, covert, and overt).

[32] Lean In & McKinsey & Company, *Women in the Workplace 2015,* 13 (2015), *http://womenintheworkplace.com/ui/pdfs/Women_in_the_Workplace_2015.pdf?v=5.*

[33] Hannah Riley Bowles & Linda Babcock, *How Can Women Escape the Compensation Negotiation Dilemma? Relational Accounts Are One Answer,* Psychology of Women Quarterly, 37.1, 81 (2013), *http://pwq.sagepub.com/content/37/1/80.full.pdf+html* (finding that "[n]egotiating for higher compensation is socially costly for women because it violates prescriptive gender stereotypes derived from the gendered division of labor . . ., and its resulting social hierarchy of men in charge and women in caregiving and support roles").

[34] Moreal Hernandez and Derek R. Avery, *Getting the Short End of the Stick: Racial Bias in Salary Negotiations,* MIT Sloan Management Review (June 15, 2016), *http://sloanreview.mit.edu/article/getting-the-short-end-of-the-stick-racial-bias-in-salary-negotiations/* (MIT conducted three studies focused on racial bias in salary negotiations. In the first study, evaluators reviewed resumes from white and black job applicants. The evaluators were asked to evaluate each job applicant and rate the likelihood that the job applicant would negotiate their salary if offered the job. After controlling for each job applicant's objective qualifications, the evaluators identified the black job applicants as less likely to negotiate compared to the white job applicants. The second study tested whether the evaluators had a racially-biased mindset, which was defined as a person who believes one or a few races were superior to others. The study found that the evaluators had different role expectations of the

Roland Fryer, Devah Pager, and Jörg L. Spenkuch found that discrimination accounts for at least one-third of the black-white wage gap.[35] The authors concluded that, compared to whites with comparable resumes, black job seekers were offered lower compensation by potential new employees and were more likely to accept the lower compensation. The researchers found that, although the wage gaps narrow over time as black workers stay at the same job, an unexplained gap nonetheless persists.[36]

Voluntary compliance is an important part of the effort to prevent discrimination and improve pay equity, and many employers are taking steps to ensure equal pay for equal work. For example, more than 25 companies have signed a White House Equal Pay Pledge to take action to reduce wage disparities in the workplace.[37] These employers committed to conducting an annual company-wide gender pay analysis across occupations, reviewing hiring and promotion processes and procedures to reduce unconscious bias and structural barriers, and embedding equal pay efforts into broader enterprise-wide equity initiatives.[38]

There is also evidence that pay equity is good for business. For example, a McKinsey & Company study found that gender parity in the United States could lead to $4.3 trillion of additional GDP by 2025, which is 19% higher than if current trends in pay inequity continue.[39] Another recent study found that, on average, companies with greater gender diversity outperformed their peers with less diversity over the previous five years, and had a higher return on equity.[40] The study measured gender diversity according to the following factors: (1) Equality in pay; (2) empowerment (defined as number of women at the highest levels of the corporation and on key committees); (3) representation of women at different levels (including as members of the board of directors, senior executives, and regular employees); (4) work life balance programs; and (5) diversity policies. Pay parity and empowerment were weighted more than the other factors.[41]

Despite voluntary compliance and the strong business case for fair pay, pay discrimination persists as a serious problem that EEOC and OFCCP are statutorily required to address. The EEOC's mission is to stop and remedy unlawful employment discrimination. The OFCCP's purpose is to enforce, for the benefit of job seekers and wage earners, the contractual promise of affirmative action and equal employment opportunity required of those who do business with the federal government. To fulfill these goals, the EEOC and OFCCP need to be as effective and efficient as possible in their investigations of alleged discrimination. They now lack the employer- and establishment-specific pay data that, prior to issuing a detailed request for information or a subpoena, would be extremely useful in helping enforcement staff to investigate potential pay discrimination. Balancing utility and burden, the EEOC has concluded that the proposed EEO–1 pay data collection would be an effective and appropriate tool for this purpose, for all of the reasons explained below.[42]

IV. Who Will Report Pay Data on the Revised EEO–1

A. Employers That Currently File the EEO–1

All private employers that are covered by Title VII and have 100 or more employees now file an EEO–1 report about the sex, race, and ethnicity of their employees, which is designated here as Component 1 (demographic data).[43] Federal contractors with 50 or more employees also file the EEO–1 if they are not exempt as provided for by 41 CFR 60–1.5. Single establishment employers file one EEO–1, and multi-establishment employers file EEO–1 reports or data for each establishment.[44] Federal contractors with 1 to 49 employees and other private employers with 1 to 99 employees do not file EEO–1 reports.

B. 60-Day Notice: Which Employers Would File Pay Data

In the 60-Day Notice, the EEOC proposed that EEO–1 private employers and federal contractors with 100 or more employees would submit the EEO–1 with pay and hours-worked data (Component 2) in addition to Component 1 data. The 60-Day Notice also stated that federal contractors with between 50 and 99 employees would continue to submit Component 1 data but would not submit Component 2 data.

C. Public Comments

The EEOC received comments urging it to remove employers with fewer than

---

black applicants compared to the white applicants and they also identified the black job applicants as less likely to negotiate. For the third study, the evaluators and job applicants were required to simulate a job negotiation. Although the black job applicants reported that they negotiated comparably (in terms of the number of offers and counteroffers made) to their white counterparts, their evaluators reported that the black job applicants had negotiated more than the white job applicants. The MIT professors concluded that because the evaluators expected the black job applicants to negotiate less, they had an exaggerated view of their behavior during the job negotiation. In addition, the professors found that the black job applicants received lower starting salaries based on the evaluators perception that the black job applicants were more aggressive).

[35] Roland Fryer, Devah Pager, and Jörg L. Spenkuch, *Racial Disparities in Job Findings and Offered Wages,* Journal of Law and Economics, University of Chicago Press, vol. 56(3), 22–23, (Sept. 2011), *http://scholar.harvard.edu/files/fryer/files/racial_disparities_in_job_finding_and_offered_wages.pdf.*

[36] *Id.*

[37] The White House, *White House Equal Pay Pledge, https://www.whitehouse.gov/webform/white-house-equal-pay-pledge. See also,* Natalia Merluzzi, *These Businesses are Taking the Equal Pay Pledge,* White House Blog (June 14, 2016), *https://www.whitehouse.gov/blog/2016/06/14/businesses-taking-equal-pay-pledge.*

[38] *Id.*

[39] McKinsey & Company, *The Power of Parity: Advancing Women's Equality in the United States,* (April 2016) *http://www.mckinsey.com/global-themes/employment-and-growth/the-power-of-parity-advancing-womens-equality-in-the-united-states.*

[40] Morgan Stanley, *Gender Diversity is a Competitive Advantage* (May 12, 2016), *http://www.morganstanley.com/blog/women/gender-diversity-work; See also* Morgan Stanley, *Why it Pays to Invest in Gender Diversity* (May 11, 2016), *http://www.morganstanley.com/ideas/gender-diversity-investment-framework.html.*

[41] *Id.*

[42] States also are addressing gender pay inequities, including proposing to establish pay transparency, prohibit retaliation against workers who discuss their wages, and request state agencies to examine their pay practices and develop best practices. For a summary of state equal pay laws, see National Conference of State Legislatures, *State Equal Pay Laws—July 2015, http://www.ncsl.org/research/labor-and-employment/equal-pay-laws.aspx.* For a summary of state equal pay legislation, see Kate Nielsen, American Association of University Women, *2015 State Equal Pay Legislation by the Numbers* (August 20, 2015), *http://www.aauw.org/2015/08/20/equal-pay-by-state/.*

[43] Private employers also must file the EEO–1 if they have fewer than 100 employees *but* are owned or affiliated with another company or have centralized ownership, control or management so that the group legally constitutes a single enterprise and the entire enterprise employs a total of 100 or more employees. EEOC, *EEO–1: Who Must File, https://www.eeoc.gov/employers/eeo1survey/whomustfile.cfm.*

[44] Employers and contractors file different types of EEO–1 reports depending on whether they are single-establishment or multi-establishment filers. Single-establishment filers only file one report, the Type 1 report. Multi-establishment filers submit several reports. These are: The Type 2—Consolidated Report, which must include data on all employees of the company; the Type 3—Headquarters Report, which must include the employees working at the main office site of the company and those who work from home and report to the corporate office; the Type 4—Establishment Report, for each physical location with *50 or more* employees, which provides full employment data categorized by race, gender and job category. For sites with fewer than 50 employees, filers submit either: Type 6—Establishment List, which provides only the establishment name, complete address and total number of employees; or Type 8—Establishment Report, which is a full report for each establishment employing *fewer than 50 employees.*

200, or fewer than 500, employees from the requirement to report pay and hours-worked data on the EEO–1 (Component 2), in order to avoid imposing a burden on them. Some comments also encouraged the EEOC to eliminate the requirement to provide establishment-level pay data for establishments with fewer than 50 or 100 employees. These comments also expressed concern that reporting pay data for small employers, or small employer establishments, could reveal employee-level pay information. Conversely, other comments urged the EEOC to collect data from smaller employers by lowering the reporting threshold for pay data to 50 or more employees for federal contractors.

D. 30-Day Notice: Employers With 100 or More Employees Will File Components 1 and 2

The Commission has considered the arguments for increasing the size of those employers subject to Components 1 and 2 and has decided to retain the same employee thresholds as in the 60-Day Notice. Exempting employers with fewer than 500 employees, or even fewer than 250, from Component 2 would result in losing data for a large number of employers who employ millions of workers, and thus would significantly reduce the utility of the pay data collection. In addition, the EEOC and OFCCP have decided not to exempt federal contractors with 50–99 employees from filing Component 1 of the EEO–1. The Commission's proposal reduces employer burden by changing other aspects of the EEO–1, such as the reporting deadline. *See* section V.

In sum, all employers with 100 or more employees will be subject to Components 1 and 2 of the EEO–1 starting with reporting year 2017. Federal contractors with 50–99 employees will not experience a change in their EEO–1 reporting requirements as a result of this proposal; they will not file Component 2 and will continue to file only Component 1. Consistent with current practice, federal contractors with 1 to 49 employees and other private employers with 1 to 99 employees will be exempt from filing the EEO–1; they will file neither Component 1 nor Component 2.

V. When To File: Filing Deadline and Workforce Snapshot Period

This 30-Day Notice proposes to change the EEO–1 filing deadline to March 31st of the year that follows the reporting year. This Notice also proposes to change the "workforce snapshot" to a pay period between October 1st and December 31st of the reporting year, starting with the EEO–1 report for 2017.

Note that the reporting schedule for 2016 data remains unchanged; EEO–1 respondents must comply with the September 30, 2016, filing requirement for the currently-approved EEO–1, and must continue to use the July 1st through September 30th workforce snapshot period for that report. Under the proposed changes to the reporting schedule, EEO–1 reports for 2017 data would be due on March 31, 2018.

A. 60-Day Notice

In the 60-Day Notice, the EEOC proposed to retain the current September 30th EEO–1 filing deadline. The EEOC explained that, starting in 2017, employers with 100 or more employees would document their employees' W–2 earnings for a 12-month period starting October 1st and ending the next September 30th. The 60-Day Notice reasoned that W–2 earnings are generally recorded in 3-month periods (calendar year quarters) and that, because the third quarter ends on September 30th, employers could calculate the 12-month W–2 wages without significant difficulty.[45] The 60-Day Notice also retained the current "workforce snapshot" approach of allowing each employer to choose a pay period between July 1st and September 30th during which it would count its employees to be reported on the EEO–1.[46] The employees counted during this pay period would be the ones reported on the EEO–1.

B. Public Comments

Employers and other groups objected vigorously to the burden of reporting non-calendar year W–2 data (*i.e.,* October 1st to September 30th). These parties argued that the EEOC, by choosing to impose this unique 12-month reporting period, would significantly increase their costs by compelling them to recalculate W–2 earnings for the sole purpose of completing the EEO–1.

On a related point, employers reliant on human resource information systems (HRIS)[47] and payroll software said that they would have insufficient time to budget, develop, and implement new reporting systems if the 2017 EEO–1 report were to be due on September 30, 2017. Employers lacking HRIS and payroll software said they would have a variety of implementation challenges, depending on how they organized their records.

Many commenters suggested changing the 12-month EEO–1 reporting period to be the same as the W–2 reporting period (a calendar year) and moving the EEO–1 filing deadline into the subsequent year, preferably after W–2s are due. A few stakeholders suggested that the EEOC conduct the pay data collection every two years.

C. 30-Day Notice

1. Deadline for Filing the EEO–1

For the upcoming 2016 EEO–1 report, the filing deadline will remain September 30, 2016. However, beginning with the 2017 report, the reporting deadline for all EEO–1 filers will be March 31st of the year following the EEO–1 report year. Thus, the 2017 EEO–1 report will be due on March 31, 2018. Changing the filing deadline will give employers subject to Component 2 six more months to prepare their recordkeeping systems for the 2017 report, and it will give them 1.5 years without filing an EEO–1 report (September 30, 2016 to March 31, 2018). At the same time, this change will align the EEO–1 with federal obligations to calculate and report W–2 earnings as of December 31st; the EEOC will not require a special W–2 calculation for the EEO–1.[48] These changes will reduce the burden on employers of gathering Component 2 data.

The Commission declines to adopt an alternate-year schedule for filing the EEO–1 report. If collected only in alternate years, the utility of EEO–1 data would be diminished because it would become stale before the new data became available.

2. "Workforce Snapshot" Period

The "workforce snapshot" period refers to the pay period when employers count the total number of employees for that year's EEO–1 report. The EEO–1 has always used this "workforce snapshot" approach, which gives employers a choice but freezes EEO–1 employment numbers as of the chosen pay period. Some employers criticized the "workforce snapshot" approach because it would not reflect same-year promotions that have the effect of moving the employee into a different EEO–1 job category or pay band after the "snapshot" was taken. The Commission addresses this concern in part by moving the "workforce snapshot" period to the fourth quarter, October 1st to December 31st, so that there are fewer opportunities for unreported changes after the "snapshot." This will preserve employer choice as to the "workforce snapshot," while at the same time accommodating the established federal schedule for preparing W–2's. In sum, while employers will count their employees during a pay period between October 1st and December 31st, they will report W–2 income and hours-worked data *for these employees* for the *entire year* ending December 31st.[49]

---

[45] 81 FR 5113 (Feb. 1, 2016).

[46] EEOC, *EEO–1: When to File, https://www.eeoc.gov/employers/eeo1survey/whentofile.cfm.*

[47] These systems are also sometimes called "human resource management systems" or HRMS.

[48] Employers must send the W–2 to the Social Security Administration by the last day of February, although special due dates apply if the employer terminated its business or is filing electronically. Employers must furnish the W–2 to employees by February 1. IRS, *Topic 752—Filing Forms W–2 and W–3* (Dec. 30, 2015), *https://www.irs.gov/taxtopics/tc752.html.*

This change will not affect the 2016 EEO–1, for which the July 1st to September 30th "workforce snapshot" period remains effective.

VI. What Pay Data To Report: Measure of Pay for the EEO–1

This 30-Day Notice proposes that employers use Box 1 of Form W–2 (hereafter "W–2 income") as the measure of pay for Component 2 of the EEO–1.[50] By definition, W–2, Box 1 includes income that is received between January 1st and December 31st of the relevant calendar year. In reaching this decision, the Commission considered government studies that analyze compensation in U.S. workplaces, relevant academic literature on compensation practices, the public comments and public testimony, and the analyses reflected in the EEOC's NAS study[51] and its own Pilot Study.[52]

A. 60-Day Notice: Options for Measuring Pay

The EEOC's 60-Day Notice described five different measures of individual compensation that are used by the federal government.[53] After narrowing its consideration to two of these—the Bureau of Labor Statistics' Occupational Employment Statistics (OES) measure of pay[54] and the Internal Revenue Service's W–2 definition[55] —the EEOC proposed to use W–2 income because it is already calculated by employers, therefore limiting burden, and because it is a comprehensive measure of pay that would be more likely to capture the effect of employment discrimination on different kinds of compensation.[56] In the 60-Day Notice, the EEOC did not specify which box on the W–2 it would use, but the Commission now specifies that employers will report on income provided in Box 1 of the W–2 form.

B. Public Comments

1. Supporting the Use of W–2 Income

Comments in support of using W–2 income emphasized that it is a comprehensive measure of pay that encompasses overtime, shift differentials, and production and non-production bonuses, which are increasingly important elements of pay. These parties stated that employment discrimination can be manifested when employers decide which employees get opportunities to earn shift differentials or overtime pay, or get large bonuses or awards. Using a measure of pay that excludes so much pay that could be influenced by discrimination would radically reduce the utility of this data collection for the EEOC and OFCCP.

2. Opposing the Use of W–2 Income

Comments in opposition to using W–2 income fell into three categories.

---

[49] By changing the EEO–1 "workforce snapshot" to the last quarter of each calendar year, EEO–1 contractor filers that also file annual employee reports under the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (VEVRAA), 38 U.S.C. 4212(d), will be in a position to align their VEVRAA data collections with the new EEO–1. Under regulations implementing VEVRAA, certain federal contractors must report annually on form VETS–4212 the number of employees and new hires protected under VEVRAA. 41 CFR 61–300.10(d)(1). Form VETS–4212 collects information for veterans protected by VEVRAA using the EEO–1's 10 job categories. For each reporting year, the federal contractor must report covered employees for the 12-month period preceding a date it selects between July 1st and August 31st that falls at the end of a payroll period. Significantly, the regulations allow contractors to select December 31st as the basis for reporting the number of employees and as the ending date of the twelve-month covered period, if the federal contractor has "previous written approval from the Equal Employment Opportunity Commission to do so for purposes of submitting the Employer Information Report EEO–1, Standard Form 100 (EEO–1 Report)." 41 CFR 61–300.10(d)(2). The implementation notice for the revised EEO–1 will serve as "previous written approval" from the EEOC pursuant to this Department of Labor VEVRAA rule.

[50] The IRS instructions for Form W–2 list the following categories of Box 1 taxable income: "(1) Total wages, bonuses (including signing bonuses), prizes, and awards paid to employees during the year; (2) Total noncash payments, including certain fringe benefits; (3) Total tips reported by the employee to the employer; (4) Certain employee business expense reimbursements; (5) The cost of accident and health insurance premiums for 2%-or-more shareholder-employees paid by an S corporation: (6) Taxable benefits from a section 125 (cafeteria) plan if the employee chooses cash; (7) Employee contributions to an Archer MSA (medical savings account); (8) Employer contributions to an Archer MSA if includible in the income of the employee; (9) Employer contributions for qualified long-term care services to the extent that such coverage is provided through a flexible spending or similar arrangement; (10) Taxable cost of group-term life insurance in excess of $50,000; (11) Unless excludable under Educational assistance programs, payments for non-job-related education expenses or for payments under a nonaccountable plan; (12) The amount includible as wages because you paid your employee's share of social security and Medicare taxes (or railroad retirement taxes, if applicable). If employer also paid the employee's income tax withholding, the employer treats the grossed-up amount of that withholding as supplemental wages and reports those wages in boxes 1, 3, 5, and 7. (Employer uses box 14 if railroad retirement taxes apply.) No exceptions to this treatment apply to household or agricultural wages; (13) Designated Roth contributions made under a section 401(k) plan, a section 403(b) salary reduction agreement, or a governmental section 457(b) plan; (14) Distributions to an employee or former employee from an NQDC plan (including a rabbi trust) or a nongovernmental section 457(b) plan; (15) Amounts includible in income under section 457(f) because the amounts are no longer subject to a substantial risk of forfeiture; (16) Payments to statutory employees who are subject to social security and Medicare taxes but not subject to federal income tax withholding must be shown in box 1 as other compensation; (17) Cost of current insurance protection under a compensatory split-dollar life insurance arrangement; (18) Employee contributions to a health savings account (HSA); (19) Employer contributions to an HSA if includible in the income of the employee; (20) Amounts includible in income under an NQDC plan because of section 409A; (21) Payments made to former employees while they are on active duty in the Armed Forces or other uniformed services; and (22) All other compensation, including certain scholarship and fellowship grants." IRS, *2016 General Instructions for Forms W–2 and W–3,* (Jan. 5, 2016), *https://www.irs.gov/pub/irs-pdf/iw2w3.pdf.*

[51] NAS Report, *supra* note 3.

[52] Sage Computing, *supra* note 3. This EEOC Pilot Study compared the OES definition of compensation to the W–2 and concluded that "[t]he W–2 definition of income . . . offers a more comprehensive picture of earnings data and therefore is more appropriate for identifying discriminatory practices." In contrast to the OES definition of pay, the W–2 definition includes all the elements of compensation that are captured by the OES definition, but also includes forms of compensation such as overtime wages, shift differentials, fees, commissions, fringe benefits, and bonuses. Box 1 on the W–2 excludes certain elective deferrals or pre-tax deductions such as employer-sponsored retirement plan (401(k) or 403(b)) contributions, flexible spending account contributions for health and dependent care, and medical contributions.

[53] NAS Report, *supra* notes 3 and 51 at 32–34, 41–45, *http://www.nap.edu/read/13496/chapter/4#32.*

[54] The Occupation Employment Statistics (OES) survey defines earnings to include base rate pay, cost-of-living allowances, guaranteed pay, hazardous-duty pay, incentive pay such as commissions and production bonuses, tips, and on-call pay. The OES measure *excludes* back pay, jury duty pay, overtime pay, severance pay, shift differentials, nonproduction bonuses, employer costs for supplementary benefits, and tuition reimbursements. U.S. Dept. of Labor, Bureau of Labor Statistics, *Occupation Employment Statistics, http://www.bls.gov/oes/current/oes_tec.htm.* OES survey uses twelve wage intervals. U.S. Dept. of Labor, Bureau of Labor Statistics, *Survey Methods and Reliability Statement for the 2015 Occupational Employment Statistics Survey,* 4, *http://www.bls.gov/oes/current/methods_statement.pdf,*

[55] 81 FR 5113, 5116 (Feb. 1, 2016). The EEOC initially considered five measures of pay. Three of those measures are used by the U.S. Bureau of Labor and Statistics (BLS) when it reports national employment data: the Occupation Employment Statistics (OES); the National Compensation Survey (NCS); and the Current Employment Statistics (CES) survey programs. One measure was from the Social Security Administration (SSA) and the final measure was from the Internal Revenue Service (IRS) (W–2).

[56] Sage Computing, *supra* notes 3 and 52.

Objection 1: W–2 Income Reflects Employee Choice and Is Not a Reliable Measure of Employer Discrimination

The most widely articulated objection to using W–2 income was that it was not indicative of discrimination because it may reflect employee choice more than employer discretion and that the EEOC cannot differentiate the two in an aggregate pay data collection. Commenters making this argument identified elective participation in overtime, working shifts that provide pay differentials, and working faster or better than another employee (*e.g.*, payments for piecework, commissions, or production), as governed by employee choice. Some of these comments argued that using W–2 income will in fact cause the EEOC to find "false-positives" indicating discrimination because the agency will assume that pay disparities are caused by discrimination rather than employee choice.

Some of these parties urged the EEOC to use "base pay" rather than W–2 income because "base pay" is controlled entirely by employers and therefore is better suited to documenting potential discrimination. Another advantage to using "base pay," they maintained, is that it would be significantly less expensive and easier for them to report on the EEO–1 because their HRIS now include records of base pay but not W–2 income. These stakeholders did not define "base pay," apart from noting that it does not include supplemental pay such as overtime, shift differentials, and bonuses, and that it can be stated as an hourly rate or as an annual salary.

Objection 2: Collection of W–2 Data Burdens Employers by Requiring the Integration of HRIS and Payroll Systems

Employers argued that reporting W–2 income would impose an inordinate burden and expense because they store W–2 income data in computerized payroll systems that are entirely separate from the HRIS where they maintain EEO–1 demographic data. They asserted that procuring or developing new software to bridge these two systems would be time-consuming and extremely costly.

Objection 3: Collection of W–2 Income Data for October 1st to September 30th Is Burdensome

Finally, employers argued that reporting W–2 income for October 1st to September 30th of every year would be burdensome because employers' payroll systems collect and report W–2 income on a calendar-year basis for tax purposes. By proposing to change the filing date for the revised EEO–1 from September 30th to March 31st, the EEOC has addressed this objection.

C. 30-Day Notice: W–2 (Box 1) Income Is the Measure of Pay

1. W–2 Income and Employee Choice

The Commission is not persuaded by the argument that W–2 income is an unsuitable measure for a pay data collection by an agency that enforces anti-discrimination laws because it may reflect employee choice as well as employer policy or decisions. As the White House Council of Economic Advisers notes, "In many situations, the delineations between discrimination and preferences are ambiguous."[57] For example, higher commission income may, as some public comments noted, reflect an employee's higher performance, but it may also reflect an employer's discriminatory assignment of more lucrative sales opportunities to employees based on race, ethnicity, and/or sex. As another example, a statistically significant difference in overtime pay between men and women in the same job may result from an employer's gender-biased assumptions that lead to more overtime opportunities being offered to men than to women, whom they may assume have competing family responsibilities. Pay discrimination is complex, and it would be an oversimplification to conclude that only those measures of pay that are shown to be exclusively dependent on an employer's decision or policy can be relevant to assessing allegations of pay discrimination.

2. Supplemental Income Is Important and May Be Linked to Discrimination

Based on its consideration of public comments and government and private sector research, the Commission concludes that supplemental pay is a critical component of compensation and it can be influenced by discrimination, so any measure of income for purposes of enforcing the pay discrimination laws should include supplemental pay. W–2 income incorporates different kinds of supplemental pay that would not be available for analysis if the EEOC were to collect only "base pay" or another basic measure of pay that ignored major sources of compensation.[58] For employers, W–2 income is a well-defined, familiar, and universally-available measure of pay; for the EEOC and OFCCP, it is useful data for exploring potential pay discrimination.

Supplemental pay is becoming more and more prevalent in the United States. As noted by the Bureau of Labor Statistics, Department of Labor (BLS), "For many occupations in the U.S. labor market supplemental pay—including overtime, bonuses, and shift differentials—is an important component of overall cash compensation. Overtime pay is especially important in production occupations and other blue-collar jobs; bonus pay is mostly a feature of high-wage managerial and sales occupations; and shift differentials play a prominent role in . . . healthcare [] and technical occupations."[59] This pattern also is apparent in some of America's highest paying professions. In the legal profession, for example, bonuses at law firms can account for a significant portion of an associate's total compensation, beyond base salary.[60]

The human resources consulting firm Aon Hewitt's 2014 U.S. Salary Increase Survey of 1,064 organizations found that variable pay (such as performance-based bonuses) for exempt employees comprised 12.7% of payroll that year.[61] This represented the highest ratio companies have paid out of their budgets toward bonuses since the consulting firm started keeping records 35 years ago and is an increase from 2008 when 10.8% of their total compensation budgets were devoted to variable pay for exempt employees.[62] Ken Abosch, leader of Aon Hewitt's compensation practice, stated that companies prefer to give performance-based pay because this practice "keeps employees focused on good performance rather than just showing up, and it allows companies to reward and retain their really valuable employees."[63] In addition, Abosch noted that performance-based pay allows companies to keep their base salaries lower and that companies will only allocate bonuses "if [the company] has good or great results."[64]

---

[57] Council of Economic Advisers Issue Brief, *The Gender Pay Gap on the Anniversary of the Lilly Ledbetter Fair Pay Act* (Jan. 2016), *https://www.whitehouse.gov/sites/default/files/page/files/20160128_cea_gender_pay_gap_issue_brief.pdf.*

[58] For example, although the FLSA requires employers to maintain pay rates, those pay rates do not include important sources of supplemental income that the EEOC has determined is important to collect in order to identify potential sources of pay discrimination.

[59] John L. Bishow, U.S. Dept. of Labor, Bureau of Labor Statistics, *A Look at Supplemental Pay: Overtime Pay, Bonuses, and Shift Differentials* (March 25, 2009), *http://www.bls.gov/opub/mlr/cwc/a-look-at-supplemental-pay-overtime-pay-bonuses-and-shift-differentials.pdf.*

[60] National Association of Law Placement (NALP), *2014 Associate Salary Survey*, NALP, 67–77 (September, 2014), Associate Bonuses.

[61] Aon Hewitt, *New Aon Hewitt Survey Shows 2014 Variable Pay Spending Spikes to Record-High Level* (Aug. 27, 2014), *http://aon.mediaroom.com/New-Aon-Hewitt-Survey-Shows-2014-Variable-Pay-Spending-Spikes-to-Record-High-Level.*

[62] *Id.*

[63] Jenna McGregor, *Bonuses are making up a bigger and bigger percentage of companies' payrolls*, Washington Post, (Aug. 27, 2014), *https://*

In some industries, shift differentials[65] and overtime pay[66] are important aspects of income. Eighty-three percent of manufacturing and production companies, 59% of customer service and support entities, and 51% of transportation and distribution companies surveyed in 2010 offered shift differentials.[67] Hospitals and health care service organizations also pay shift differentials for holiday and weekend shifts more than other industries.[68] Overtime is particularly important in production, transportation, and material moving industries, with workers earning 2% of their income in overtime pay in December 2015.[69] Employers can control who gets the opportunity for assignments to lucrative shifts that pay premium wages or overtime pay, and withholding such assignments because of a protected basis such as race, ethnicity, or sex would violate Title VII.

Incentive pay for top executives also may be subject to discrimination. For example, at the five highest executive level positions (chief executive officer, vice chair, president, chief financial officer, and chief operating officer), research based on data from 1992–2005 shows that women received a lower share of incentive pay (including bonuses and stock option grants) than their male counterparts, accounting for 93% of the gender pay gap at that level.[70] This difference remained even after taking into account differences of age, tenure, and titles.[71]

3. Bridging HRIS and Payroll

In light of employers' argument that bridging employers' HRIS and payroll software for the new EEO–1 will be so burdensome that it outweighs the utility of W–2 income, the EEOC examined three of the HRIS tools that it sees most often in systemic investigations: ADP Enterprise, PeopleSoft, and UltiPro. All three HRIS allow for the collection of EEO–1 demographic data, and all three offer the capacity to record year-to-date gross and paid earnings.[72] The EEOC recognizes that many employers may not choose to use this capacity, but its existence suggests that creating software solutions for the EEO–1, Components 1 and 2, may not be as complex or novel as some comments suggested.

The EEOC intends to support employers and HRIS vendors as appropriate to accommodate Component 2 of the proposed EEO–1. For example, the EEO–1 Joint Reporting Committee plans to post online its new Data File Specifications for Components 1 and 2 of the modified EEO–1 as soon as OMB approves the information collection. The EEO–1 data file specifications will be for data uploads (submitting EEO–1 data in one digital file), but they also will describe the formatting of data for direct data entry onto the firm's secure EEO–1 account with the Joint Reporting Committee. For reference, the current EEO–1 data file specifications can be found at *https://www.eeoc.gov/employers/eeo1survey/ee1_datafile_2013.cfm.*

VII. What Data To Report: Hours Worked

A. 60-Day Notice

The Commission proposed collecting the number of "hours worked" for non-exempt employees by job category, subdivided into pay band cells, to account for periods when employees were not employed or were engaged in part-time work. With regard to exempt employees, the EEOC suggested that "[o]ne approach would be for employers to use an estimate of 40 hours per week for full-time salaried workers. The EEOC [was] not proposing to require an employer to begin collecting additional data on actual hours worked for salaried workers, to the extent that the employer does not currently maintain such information."[73]

B. Public Comments

Public comments from many employers objected to collecting hours worked data due to the cost of creating new systems to collate and report data about hours worked with W–2 income, and EEO–1 Component 1 data. Some employers inquired how the EEOC would define "hours worked," so they would know what to report. These employers focused on two alternatives: (1) The FLSA definition of hours worked; and (2) the Affordable Care Act (ACA) approach.

The question of how to count hours worked for employees exempt from overtime received a lot of attention, especially the EEOC's proposal to count 40 hours per week for full time, exempt workers. Supporters of the revised EEO–1 said it was reasonable to use a proxy of 40 hours per week for full-time exempt employees. Those who objected to using the 40-hours per week proxy observed that it simply would not reflect the reality of the hours worked by many full-time exempt employees, who may work substantially more than 40 hours in any given week and may work less than 40 hours in another week. Some comments argued that, since the 40-hour estimate would be incorrect in many instances, reporting 40 hours per week would require them to submit and certify inaccurate information to the federal government.

C. 30-Day Notice

1. The Importance of Collecting Hours Worked

Collecting hours worked is of central importance because this data will enable the EEOC and OFCCP to account for part-time and partial-year work and to assess potential pay disparities in the

---

www.washingtonpost.com/news/on-leadership/wp/2014/08/27/bonuses-are-making-up-a-bigger-and-bigger-percentage-of-companies-payrolls/.

[64] *Id.*

[65] Shift differentials are paid to compensate employees for working shifts other than regular weekday hours.

[66] Employees who are nonexempt under the Fair Labor Standards Act are entitled to receive overtime pay for hours worked over 40 in a workweek. 29 CFR 778.10. The overtime rate is not less than time and one-half their regular pay rate. U.S. Dept. of Labor, Wage and Hour Division, *Overtime Pay, https://www.dol.gov/whd/overtime_pay.htm. See also* U.S. Dept. of Labor, Wage and Hour Division, *Final Rule: Overtime, https://www.dol.gov/whd/overtime/final2016/,* and, U.S. Dept. of Labor, Wage and Hour Division, *Fact Sheet: Final Rule to Update the Regulations Defining and Delimiting the Exemption for Executive, Administrative, and Professional Employees* (May 2016), *https://www.dol.gov/whd/overtime/final2016/overtime-factsheet.htm.*

[67] SHRM, *Shift Differentials: Compensation for Working Undesirable Hours* (Dec. 3, 2010), *https://www.shrm.org/hrdisciplines/compensation/articles/pages/shiftdifferentials.aspx.*

[68] *Id.*

[69] U.S. Dept. of Labor, Bureau of Labor Statistics, *News Release-Employer Costs for Employee Compensation* (June 9, 2016), *http://www.bls.gov/news.release/pdf/ecec.pdf.*

[70] Stefania Albanesi, Claudia Olivetti, Maria José Prados, *Liberty Street Economics: Incentive Pay and Gender Compensation Gaps for Top Executives,* Federal Reserve Bank of New York, (Aug. 25, 2015), *http://libertystreeteconomics.newyorkfed.org/2015/08/incentive-pay-and-gender-compensation-gaps-for-top-executives.html#.VzovwP5JlR0.*

[71] Stefania Albanesi, *How performance pay schemes make the gender gap worse,* World Economic Forum, (Dec.23, 2015), *https://www.weforum.org/agenda/2015/12/how-performance-pay-schemes-make-the-gender-gap-worse/.*

[72] The ADP HRIS software allows for the collection of year-to-date gross pay and pay earnings. It includes paycheck year-to-date totals and provides fields for year-to-date tax amount, overtime hourly earnings, overtime hours, total overtime earnings, and total overtime hours. Further, it appears to provide fields for year-to-date taxable income, taxable gross income year-to-date, and year-to-date taxable amounts. Ultipro allows collection of weekly pay rate, hourly pay rate, and year-to-date taxable gross income, in addition to other measure of pay, hours, and bonus. Finally, PeopleSoft allows collection of hourly rate, minimum hourly rate, maximum hourly rate, and Last 26 Pay Period gross income.

[73] 81 FR 5113, 5117 (Feb. 1, 2016).

context of this information. The importance of "hours worked" data can be illustrated by example. If two men and two women in the same job category are paid comparable wage rates, but the men are employed full-time and the women are employed part-time, it would initially appear on Component 2 of the EEO–1—without any data on their hours worked—that the employer was paying the women significantly less than the men (the women would be counted in a lower pay band). On the other hand, if it was known that the men worked 40 hours per week and the women worked 20 hours per week, then their different hours would provide a potential explanation of what initially appears to be a gender-based pay disparity. Of course, explaining a pay disparity in this way would not rule out the possibility that it was also caused by a discriminatory practice or policy that may be identified through further investigation.

In addition to helping to assess pay disparities, hours-worked data may be useful in its own right. The EEOC receives charges of discrimination alleging that an employer gave the charging party fewer hours than other employees, or denied overtime or premium pay hours based on race, ethnicity, sex, or another statutorily-protected basis. Collecting "hours worked" data on the EEO–1 would be useful in the initial stages of such an investigation, as the EEOC seeks to assess how the employer assigns work hours.

2. Defining "Hours Worked"

The Commission adopts the FLSA definition for "hours worked" because it is familiar to employers, designed in conjunction with pay, and applies to all employers subject to the EEO–1.[74] By contrast, the ACA approach to "service hours" gives employers a range of choices about how to count hours, which would not provide clarity for the EEO–1.[75]

Under the FLSA, the term "hours worked" includes "all time an employee must be on duty, or on the employer's premises or at any other prescribed place of work, from the beginning of the first principal activity of the workday to the end of the last principal activity of the workday."[76] Numerous court decisions have also helped shape this definition. The FLSA and its regulations require employers to maintain certain records for nonexempt employees, including hours the employee worked each day and the total hours the employee worked each workweek.[77] Payroll records are to be preserved for at least three years and records upon which wage computations were made (*e.g.*, time cards) should be maintained for at least two years.[78]

Federal contractors that file the EEO–1 also are subject to the 2014 Fair Pay and Safe Workplaces Executive Order, which, once implemented by regulation, will require them to supply employees with a document each pay period showing the employee's hours worked, overtime hours, pay, and any additions made to, or deductions made from, pay as recorded for purposes of the FLSA.[79] Adopting the FLSA definition of "hours worked" for the EEO–1 promotes consistency for contractors subject to both requirements.

3. Reporting Hours Worked for Nonexempt Employees

The Commission will require private employers and contractors to report the "hours worked" as recorded for FLSA purposes for nonexempt employees in Component 2 of the proposed EEO–1. "Hours worked" will be reported for the total number of employees in each pay band by ethnicity, race, and gender, for the entire calendar year. For example, assume an employer reports on the EEO–1 that it employs four African American women as administrative support workers in the sixth pay band. The employer would report their total "hours worked" for the entire year in the appropriate pay band cell under "Hours Worked" (for example, 8,160 hours). If one of the workers resigned after the employer took its "workforce snapshot" but before December 31st, the employer would report only the total number of hours she actually worked that year prior to her resignation, which would account for her partial-year employment (for example, rather than 2,040 hours, it might report 1,900 hours).

4. Reporting Hours Worked for Exempt Employees

Although the Commission seeks to minimize employer burden, the importance of hours-worked data necessitates its collection on the EEO–1. The EEO–1 Instructions will give employers the option to: (1) Report a proxy of 40 hours per week for full-time exempt employees, and 20 hours per week for part-time exempt employees, multiplied by the number of weeks the individuals were employed during the EEO–1 reporting year; or (2) provide actual hours of work by exempt employees during the EEO–1 reporting year if the employer already maintains accurate records of this information.

---

[74] Under the Fair Labor Standards Act, employers must keep certain records for employees who are subject to the minimum wage provisions alone, or to both the minimum wage and overtime provisions, including records of hours worked each workday and total hours worked each workweek. 29 CFR 516.2(a)(7). Employers are not required to maintain hours worked records for employees who are exempt from minimum wage or minimum wage and overtime requirements. 29 CFR 516.3. "Hours worked" under the FLSA includes "(a) [a]ll time during which an employee is required to be on duty or on the employer's premises or at a prescribed workplace and (b) all time during which an employee is suffered or permitted to work whether or not he is required to do so." 29 CFR 778.223. Unlike the ACA definition, it does not include paid days off.

[75] Under the Affordable Care Act (ACA), all employers with 50 or more full-time employees or equivalents are considered applicable large employers (ALEs) subject to ACA's shared responsibility provisions for providing health insurance. For this purpose, a full-time employee is, for a calendar month, an employee employed on average at least 30 hours of service per week, or 130 hours of service per month. The ACA provides employers the flexibility to use different measurements of hours worked, or "service hours," for different categories of exempt employees, provided the measures are reasonable and consistently applied. 26 CFR 54.4980H–3(b)(3)(i).

[76] U.S. Dept. of Labor, Wage and Hour Division, *Handy Reference Guide to the Fair Labor Standards Act* (November, 2014), *https://www.dol.gov/whd/regs/compliance/hrg.htm.*

[77] Additional FLSA recordkeeping requirements include (1) the employee's sex and occupation, (2) time and day of the week when employer's workweek begins, (3) basis on which employee's wages are paid, (4) employee's regular hourly rate, (5) employee's total daily or weekly straight-time earnings, (6) employee's total overtime earnings for the workweek, (7) employee's total wages each pay period, (8) date of payment to employee and pay period covered by payment, and much more. 29 CFR 516. *See also* United States Department of Labor, Wage and Hour Division, *Fact Sheet #21: Recordkeeping Requirements under the Fair Labor Standards Act (FLSA)* (July, 2008), *https://www.dol.gov/whd/regs/compliance/whdfs21.htm.*

[78] *Id.*

[79] E.O. 13673, section 5, 79 FR 45309 (Aug. 5, 2014). The Paycheck Transparency provision of the Executive Order on Fair Pay Safe Workplaces provides: "(a) Agencies shall ensure that, for contracts subject to section 2 of this order, provisions in solicitations and clauses in contracts shall provide that, in each pay period, contractors provide all individuals performing work under the contract for whom they are required to maintain wage records under the Fair Labor Standards Act; 40 U.S.C. chapter 31, subchapter IV (also known as the Davis-Bacon Act); 41 U.S.C. chapter 67 (also known as the Service Contract Act); or equivalent State laws, with a document with information concerning that individual's hours worked, overtime hours, pay, and any additions made to or deductions made from pay. Agencies shall also require that contractors incorporate this same requirement into subcontracts covered by section 2 of this order. The document provided to individuals exempt from the overtime compensation requirements of the Fair Labor Standards Act need not include a record of hours worked if the contractor informs the individuals of their overtime exempt status. These requirements shall be deemed to be fulfilled if the contractor is complying with State or local requirements that the Secretary of Labor has determined are substantially similar to those required by this subsection."

With this approach, the company official who certifies the firm's EEO–1 report would certify that the reports are "accurate and . . . . prepared in accordance with the instructions." Since the new EEO–1 instructions will give employers the option to record 40 hours per week for full-time exempt employees and 20 hours per week for part-time exempt employees, or to report actual hours-worked data for exempt employees, employers using the proxies can certify with confidence that they completed their EEO–1 reports accurately and in accordance with the instructions.

VIII. How To Report Data in Component 2: Pay Bands and Job Categories

This 30-Day Notice does not change the proposal to collect W–2 income and hours-worked data in the twelve pay bands used by the Department of Labor's Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES),[80] for each of the 10 EEO–1 job categories. Such data will support the EEOC's ability to discern significant pay disparities in the early stages of its investigations and, in conjunction with other information, to make more efficient decisions about how to plan the investigations going forward.

A. 60-Day Notice

The 60-Day Notice proposed that Component 2 of the EEO–1 report would collect W–2 income and hours-worked data within twelve distinct pay bands for each job category. These pay bands were based on the twelve wage intervals used by the BLS for the OES survey, which is a semi-annual survey designed to measure employment and wage estimates[81] for over 800 occupations.[82] These OES pay bands are different from the pay bands used on the EEO–4 report now completed by state and local government employers.

TABLE 1—EEO–4 PAY BANDS

Pay bands	Pay bands label
1	$100–$15,999.
2	$16,000–$19,999.
3	$20,000–$24,999.
4	$25,000–$32,999.
5	$33,000–$42,999.
6	$43,000–$54,999.
7	$55,000–$69,999.
8	$70,000 and over.

TABLE 2—PROPOSED EEO–1 PAY BANDS

Pay bands	Pay bands label
1	$19,239 and under.
2	$19,240–$24,439.
3	$24,440–$30,679.
4	$30,680–$38,999.
5	$39,000–$49,919.
6	$49,920–$62,919.
7	$62,920–$80,079.
8	$80,080–$101,919.
9	$101,920–$128,959.
10	$128,960–$163,799.
11	$163,800–$207,999.
12	$208,000 and over.

B. Public Comments

Many stakeholders argued that the twelve OES pay bands are overly broad, particularly for the highest pay band ($208,000 and over) and also for the lower or middle income pay bands ($30,000 to $80,000). Opponents of the proposal argued that broad pay bands would not produce reliable data because the employees within each pay band may have different levels of experience or hold different jobs within an organization. Some comments advocated for additional and narrower pay bands to better capture pay disparities.

C. 30-Day Notice

Collecting W–2 income and hours-worked data in the twelve OES pay bands will enable the EEOC to gather pay data about most employees and EEO–1 filers, as the majority of wages in the United States are well below the highest OES pay band ($208,000 and over), even after including some types of supplemental income. According to the U.S. Census Bureau, the estimated median earnings for full-time, year round civilian workers 16 years of age and over were $43,545 in 2014. For management occupations, the median earnings were $71,112.[83]

In Component 2 of the EEO–1, employers will report the number of employees whose annual W–2 income falls in each of the job category's twelve pay bands. For example, an employer may report that it has twelve employees in pay band 3 for Professionals, and that four are white men, four are Asian men, and four are white women.

The EEOC is not convinced that using twelve pay bands in conjunction with the EEO–1 job categories will undermine the utility of W–2 income and hours-worked data. The EEOC does not intend or expect that this data will identify specific, similarly situated comparators or that it will establish pay discrimination as a legal matter. Therefore, it is not critical that each EEO–1 pay band include only the same or similar occupations. The data will be useful for identifying patterns or correlations that can inform the early stages of the investigative process, as explained in more detail in section IX.

In addition, many EEO–1 firms and establishments do not report widely divergent occupations in each EEO–1 job category. It also is likely that similar firms and establishments in the same geographic area will have similar distributions of occupations within the job groups and pay bands, thus making statistical comparisons between EEO–1 reports a reasonable approach to using this data.

IX. How the EEOC Will Use W–2 and Hours-Worked Data

A. 60-Day Notice

As explained in the 60-Day Notice, Component 2 data would support EEOC data analysis at the early stages of an investigation, using statistical tests to identify significant disparities in reported pay. EEOC enforcement staff who conduct these analyses would use them, in the larger context of other available economic data and information, to evaluate whether and how to investigate the allegations of discrimination in more depth. Moreover, the 60-Day Notice also explained how employers would be able to use the summary pay data that the EEOC intends to publish to generally assess their own pay practices.

B. Public Comments

Employers opposing the proposal expressed concern that the EEOC would make unfounded inferences of discrimination based on its statistical analysis of the EEO–1 Component 2 pay data which, in turn, would result in unwarranted and burdensome EEOC investigations. Some interested parties criticized the particular statistical analyses that the EEOC described in the 60-Day Notice, arguing that these tests would not yield meaningful results when applied to data reported in pay bands and broad EEO–1 job categories. These commenters also raised concerns about the dangers of Type I or Type II errors in analyzing Component 2 data: In statistics, "Type I" errors are referred to as "false positives" and "Type II" errors are "false negatives."[84]

---

[80] U.S. Dept. of Labor, Bureau of Labor Statistics, *Survey Methods and Reliability Statement for the May 2015 Occupational Employment Statistics Survey, supra* note 54 at 3, (stating that "employment refers to the number of workers who can be classified as full-or-part-time employees, including workers on paid vacations or other types of paid leave; exempt officers, executives, and staff members of incorporated firms; employees temporarily assigned to other units; and noncontract employees for whom the reporting unit is their permanent duty station regardless of whether that unit prepares their paychecks.")

[81] U.S. Dept. of Labor, Bureau of Labor Statistics, *Occupational Employment Statistics Frequently Asked Questions, http://www.bls.gov/oes/oes_ques.htm.*

[82] *Id.* The OES survey produces estimates of wages or salary paid to employees in non-farm occupations in the United States, in a particular State, or in a particular industry. The occupational wage estimates can be estimates of mean wages or percentiles, such as the median wage.

[83] U.S. Census Bureau, *Table Packages,* Full-Time, Year-Round Workers and Median Earnings in the Past 12 Months by Sex and Detailed Occupation: 2014, *http://www.census.gov/people/io/publications/table_packages.html.*

Finally, employers expressed skepticism that the EEOC's reports based on aggregated EEO–1 pay data would be useful for evaluating their own pay practices and promoting voluntary compliance. Several employers explained that they do not use W–2 data to analyze their own compensation practices, but rather rely on more complete compensation data that they have at their disposal.

C. 30-Day Notice

This 30-Day Notice expands on the discussion in the 60-Day Notice and explains in more detail how the data collected with this information collection will support enforcement of, and compliance with, Title VII, the EPA, and E.O. 11246.

1. Early Assessment of Charges of Discrimination

Currently, the EEOC enforcement staff can retrieve a respondent's EEO–1 report using existing EEO–1 analytics software to assess the distribution of different demographics (sex, race, and ethnicity) in an employer's job groups. When W–2 income and hours-worked data is added to the EEO–1 report, the EEOC's EEO–1 analytic software tool will be expanded to allow for the examination of pay disparities based on job category, pay bands, and gender, ethnicity, or race. For example, if a charging party alleges that she was paid less than her male colleagues in a similar job, the EEOC's enforcement staff might use the expanded EEO–1 analytics tool to generate a report comparing the distribution of the pay of women to that of men in the same EEO–1 job category.[85] They also might use statistical tools to determine generally whether there are significant disparities in reported pay in job groups based on race, gender, or ethnicity.

EEOC enforcement staff could then examine how the employer compares to similar employers in its labor market[86] by using a statistical test to compare the distribution of women's pay in the respondent's EEO–1 report to the distribution of women's pay among the respondent's competitors in the same labor market. With the proposed addition of hours-worked data to the EEO–1, statistical tests could be used to determine whether pay disparities remain among relevant groups such as men and women, controlling for hours worked. More specifically, statistical tests could determine whether factors such as race, ethnicity, gender, and hours worked impact the distribution of individuals in pay bands. The EEOC envisions that any statistical test would be accompanied by an indication of the practical significance of pay differences.

After considering the results of several statistical analyses in conjunction with allegations in the charge, and sometimes also assessing how the EEO–1 pay data compares to statistics for comparable workers using Census data, EEOC enforcement staff would decide how to focus the investigation and what information to request from the employer. When EEOC enforcement staff requests information from an employer, the employer has the opportunity to explain its practices, provide additional data, and explain the non-discriminatory reasons for its pay practices and decisions. Only after considering all of this information, and possibly additional information, would the EEOC reach a conclusion about whether discrimination was the likely cause of the pay disparities.

The EEOC has tested whether statistical tests, and the EEO–1 pay data, would be useful tools in the investigation of charges of discrimination and has found them to be effective.[87] The EEOC used two databases to test the utility of the planned analyses. The first was the EEO–4 database that the EEOC currently uses to collect and analyze pay data from state and local governments. Since the EEO–4 has fewer and different pay bands than the EEOC proposes for the EEO–1 pay data collection, the EEOC also used a synthetic database. The term "synthetic" does not mean that the data was not real. Rather, the EEOC created a large confidential database from HRIS data obtained in actual EEOC investigations that contained certain variables of interest, in particular pay rate history and job titles for all employees, and the statistical tests referenced above were run. Other important variables such as "race," "gender," and "EEO–1" job codes were randomly generated for databases that lacked this information. The results supported the EEOC's conclusion that these statistical tests provide insights that are useful in developing a request for information or deciding whether an investigation of a charge should have a more limited scope.[88]

As noted above, some critics disputed the EEOC's choice of statistical tests, arguing that they would not be useful for data reported in broad pay bands and job categories. The EEOC's Pilot Study reported on a 2007 study finding that, even if collecting income data in bands results in a loss of information, that loss would likely be small and of little concern to many researchers, and would be balanced by reduced cost and burden.[89] Other researchers have identified the value of banded pay data even to the point of being useful in estimating mean incomes within an accuracy of 1–3 percent.[90] This research suggests that critics who argue that one cannot detect mean differences that are smaller than the pay bands, or bins, are incorrect.[91]

In addition, the EEOC is confident that the risk of Type I (false positive) or Type II (false negative) errors will not undermine its statistical analyses of Component 2 data. The chances of incurring Type I errors (false positives) are related to the probability level used in the statistical significance test. The EEOC follows judicially recognized statistical standards for identifying meaningful discrepancies,[92] and therefore is confident that the probability level it uses is effective at minimizing the risk of Type I (false positive) errors. By contrast, the risk of Type II (false negative) error is inversely related to the sample size: The smaller the sample size, the more likely a Type II error. If a sample size is so small that the EEOC enforcement staff is concerned about Type II errors, it will consider analyzing a differently configured, larger sample. Even if it forgoes such analysis due to an elevated risk of Type II errors, enforcement staff will study the EEO–1 for other relevant information and analyze additional data from other sources. In fact, EEOC enforcement staff expects to analyze data from other sources regardless of the risk of error.

---

[84] Type I errors represent the possibility of rejecting a null hypothesis when it is correct. For example, a null hypothesis might be that the earnings of African Americans and whites are the same and a Type I error would be rejecting it as false when it is true. Type II errors represent the opposite: The possibility of accepting the null hypothesis (for example, that the earnings of African Americans and whites are the same) as true when in fact it is false. Type I errors in this context could suggest a need for an investigation where it may not be needed; Type II errors in this context could result in victims of pay discrimination not receiving relief for discrimination.

[85] Enforcement staff could choose to compare men and women in one particular EEO–1 job category, for multiple job categories, or even all job categories.

[86] EEO–1 reports are identified by location and by each establishment's 5-dight NAICS industry codes. The U.S. Census Bureau maintains only one NAICS code for each establishment based on its primary business activity. The Census Bureau states: "[i]deally, the primary business activity of an establishment is determined by relative share of production costs and/or capital investment. In practice, other variables, such as revenue, value of shipments, or employment, are used as proxies. The Census Bureau generally uses revenue or value of shipments to determine an establishment's primary business activity." U.S. Census Bureau, "*North American Industry Classification System—Frequently Asked Questions*," *https://www.census.gov/eos/www/naics/faqs/faqs.html.*

[87] Sage Computing, *supra* notes 3, 52, and 56.

[88] *Id.*

[89] *Id.* citing Micklewright, John and Schnepf, Sylke V., *How Reliable are Income Data Collected with a Single Question?* (Nov., 2007), *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1047981.*

[90] Paul T. von Hippel, Samuel V. Scarpino and Igor Holas, *Robust estimation of inequality from binned incomes,* Sociological Methodology (Jun. 6, 2016), *http://arxiv.org/abs/1402.4061.*

[91] *Id.*

2. EEOC Publications Analyzing Aggregate EEO–1 Data

Using aggregated EEO–1 data, Census data, and potentially other data sources, the EEOC expects to periodically publish reports on pay disparities by race, sex, industry, occupational groupings, and Metropolitan Statistical Area (MSA). Particularly after a few years of data collection, these reports will provide useful comparative data. For smaller employers and others that do not hire consultants to analyze their compensation structures, these reports will be especially informative in light of the business case for equal pay and the need to comply with state equal pay laws.

The EEOC's publication of aggregated pay data, in conjunction with the employer's preparation of the EEO–1 report itself, may be useful tools for employers to engage in voluntary self-assessment of pay practices. For contractors, such self-assessment is encouraged by the OFCCP Rule on Discrimination on the Basis of Sex.[93] OFCCP states that “[e]ach contractor may continue to choose the assessment method that best fits with its workforce and compensation practices.”[94] Although the OFCCP rule does not create new obligations with respect to a covered contractor's self-assessment of its compensation practices, it does provide additional guidance about the kinds of compensation practices the contractors should evaluate to ensure their compliance with E.O. 11246.

3. EEOC Training on the Pay Data Collection

The EEOC will ensure its internal capacity to use the EEO–1 pay data effectively by supplementing existing training for EEOC statisticians, investigators, and attorneys about how EEO–1 pay data and the updated EEO–1 analytics tool can be used to improve the agency's enforcement work. EEOC enforcement staff will receive periodic training on how to use the expanded EEO–1 analytics software tool to examine pay data and identify any disparities. EEOC personnel who conduct intake also would receive periodic training to help them “issue spot” potential pay discrimination and ask appropriate questions to collect relevant anecdotal evidence of possible discrimination and information about employer policies and practices. Further, the agency would provide specialized training to its lead systemic investigators. Finally, as discussed more fully below, the EEOC would continue to ensure that staff is trained with regard to confidentiality obligations with respect to pay data.

The EEOC also would provide enhanced technical assistance and support to employers with seminars or webinars, training, and outreach and education materials. Such materials may include best practice guides and self-assessment tools to promote voluntary compliance and assist employers in identifying and correcting discriminatory pay policies and practices. They may also identify practices that could lead to pay discrimination, such as subjective pay decision-making practices, establishing salary by relying heavily on prior salary, and setting salary based in large part on negotiations.

Finally, the EEOC would conduct outreach to other stakeholders, including employees and their advocates, and academic researchers. Outreach to employees and their advocates would focus on “know your rights” trainings with respect to equal pay for equal work and also include training about how to use the EEOC's planned aggregated pay data reports for research and informational purposes.

X. Confidentiality of EEO–1 Data

This 30-Day Notice expands on the discussion in the 60-Day Notice regarding the privacy and confidentiality protections for Component 2 data. The EEOC has successfully protected the confidentiality of EEO–1 data for over 50 years, since this data was first collected. Recognizing that employers are concerned both about the confidentiality of their business data and the privacy of employees' pay information, the EEOC and OFCCP have committed to vigorously guarding its privacy and confidentiality, as explained below.

A. 60-Day Notice

The 60-Day Notice emphasized that Title VII subjects the EEOC to strict confidentiality requirements, subject to criminal penalties; that OFCCP defers to the EEOC on disclosure of all non-contractor data; and that the OFCCP ensures the confidentiality of contractor data to the maximum extent permissible by law. In the 60-Day Notice, the EEOC explained that EEO–1 Component 2 data would not include any employee personally identifiable information and, since EEO–1 pay and hours-worked data would be anonymous and aggregated, personally identifying information would not be readily apparent.

B. Public Comments

Employers expressed concern that the addition of sensitive pay data to the EEO–1 would make it more valuable to their competitors and that any breach in confidentiality would be significantly more costly than with the current EEO–1. They also expressed concern about the privacy of the data, because an individual's pay could be disclosed if, for example, the employee was one of only a few employees matching a particular race/ethnicity background and gender in a cell on the EEO–1 and the EEO–1 report were disclosed. Some employers expressed concern that federal and state agencies may not be bound by Title VII's confidentiality requirements, and some employers urged the EEOC to prevail on Congress to amend Title VII to expressly extend the statute's confidentiality provisions to other federal and state agencies that might get EEO–1 data.

C. 30-Day Notice

1. Legal Confidentiality

a. EEOC

As recognized by employers and explained in the 60-Day Notice, Title VII forbids the EEOC or any EEOC officer or employee from making public any information, including EEO–1 data, before a Title VII proceeding is instituted that involves that information.[95] EEOC staff who violate this prohibition are guilty of a criminal misdemeanor and can be imprisoned.

---

[92] *Hazelwood Sch. Dist.* v. *United States,* 433 U.S. 299, 311 n.17 (1977) (explaining that “a fluctuation of more than two or three standard deviations would undercut the hypothesis that decisions were being made randomly with respect to [a protected trait]”); *Wright* v. *Stern,* 450 F.Supp.2d 335, 363 (S.D.N.Y. 2006) (denying motion for summary judgment in case alleging discrimination against African-American and Hispanic employees in promotions and compensation, the court noted that, “[t]hough not dispositive, statistics demonstrating a disparity of two standard deviations outside of the norm are generally considered statistically significant.”).

[93] 41 CFR 60–20. *See also* 81 FR 39109 (June 15, 2016).

[94] *Id.*

The EEOC directly imposes this Title VII confidentiality requirement on all of its contractors, including contract workers and contractor companies, as a condition of their contracts. With respect to other federal agencies with a legitimate law enforcement purpose, the EEOC gives access to information collected under Title VII *only* if the agencies agree, by letter or memorandum of understanding, to comply with the confidentiality provisions of Title VII.

Finally, the text of Title VII itself states that the EEOC may only give state and local fair employment practices agencies (FEPAs) information (including EEO–1 data) about employers in their jurisdiction on the condition that they *not* make it public.[96]

For the EEOC, its agents and contractors, and the FEPAs, Title VII only permits disclosure of information after suit is filed on the issues that were investigated at the administrative level.

b. OFCCP

Even though OFCCP obtains EEO–1 reports for federal contractors and subcontractors (contractors) through the Joint Reporting Committee with the EEOC, OFCCP obtains this information pursuant to its own legal authority under E.O. 11246 and its implementing regulations.[97]

OFCCP will notify contractors of any FOIA request for their EEO–1 pay and hours-worked data. If a contractor objects to disclosure, OFCCP will not disclose the data if OFCCP determines that the contractor's objection is valid. FOIA Exemptions 3 and 4 recognize the value of this data and provide, in combination with the Trade Secrets Act, the necessary tools to appropriately protect it from public disclosure. OFCCP will protect the confidentiality of EEO–1 pay and hours-worked data to the maximum extent possible consistent with FOIA.

With respect to companies that are not federal contractors or subcontractors under OFCCP's jurisdiction, the confidentiality provision of Section 709(e) applies. OFCCP will refer all such FOIA requests for EEO–1 data to the EEOC for a response. The EEOC, in turn, is subject to Title VII confidentiality and cannot disclose any of its EEO–1 data to the public, except in an aggregated format that protects the confidentiality of each employer's information. Any FOIA request by a member of the public for such disaggregated EEO–1 data will be denied by the EEOC under Exemption 3 of the FOIA.

2. Data Protection and Security

The EEOC takes extensive measures to protect the confidentiality and integrity of EEO–1 data in its possession. First, all EEOC and FEPA staff[98] receive annual training in data protection and security. The EEOC maintains a robust cyber security and privacy program, in compliance with the Federal Information Security Modernization Act of 2014.[99]

The EEOC also complies with a comprehensive set of security and privacy controls to protect organizational operations and information system assets against a diverse set of threats, including hostile cyber-attacks, natural disasters, structural failures, and human errors. The EEOC's systems are monitored on an ongoing basis to assure compliance with an extensive set of security and privacy requirements derived from legislation, Executive Orders, policies, directives, and standards.[100] Agency information technology systems are subjected to weekly security scans by the Department of Homeland Security, annual internal audits performed by the EEOC's Office of Inspector General, and expert third-party audits for best practices and compliance with cyber-security standards. Current protections include regular internal and external vulnerability scanning and penetration testing, comprehensive real-time anti-virus scanning and protection on all desktops and servers, Internet and email filtering for malware and spam, strong firewall protections and intrusion detection systems, compliance with security benchmark configuration settings, deep discovery advanced network security analysis and monitoring, secure domain name server configurations, automatic server/firewall monitoring and logging, security awareness training, and comprehensive disaster recovery planning and testing.

The online EEO–1 portal of the Joint Reporting Committee allows firms that currently upload EEO–1 data files to encrypt their data or even create a file transfer site for EEOC to download the data. After collecting and reconciling EEO–1 data through a process that may involve input from the employer or contractor, the Joint Reporting Committee at the EEOC provides the database to OFCCP on an encrypted storage device.

XI. Paperwork Reduction Act Burden Estimates

A. Background

The revised EEO–1 data collection has two components. The first component (Component 1) will collect information identical to that collected by the currently approved EEO–1, through which employers report data on employees' ethnicity, race, and sex by job category. The second component (Component 2) will collect data on employees' W–2 (Box 1) income and hours worked. Because of the complexity of this PRA burden calculation, the EEOC is providing the following background information to explain the rationale behind its methodologies for calculating the annual and one-time burden of filing EEO–1 reports.

The OMB's PRA guidance prescribes the factors for agencies to consider in calculating annual reporting and one-time implementation costs. The prescribed PRA calculation is focused on the time it takes filers to complete the tasks required for the proposed information collection and the hourly rates of the employees who spend that time. For this reason, the following discussion of the costs of transitioning and annually filing Components 1 and 2 of the EEO–1 must be formulated through the PRA analysis of hours spent and hourly rates.

OMB's PRA regulations also require consideration of how to reduce the burden of a data collection through the use of technology and automation.[101]

---

[95] 42 U.S.C. 2000e–8(e).

[96] 42 U.S.C. 2000e–8(d). *See also* EEOC, *EEO–1 Survey System Privacy Impact Assessment, https://www.eeoc.gov/employers/eeo1survey/privacyimpact.cfm.*

[97] 41 CFR 60–1.7(a)(1).

[98] As noted in text above, all FEPAs sign a contractual agreement with the EEOC that requires them to follow the confidentiality provisions set forth in Title VII.

[99] 44 U.S.C. 3551; *see also* relevant provision 44 U.S.C. 3554 discussing federal agency responsibilities for protecting federal information and information systems.

[100] 40 U.S.C. 1401 *et seq.*, Information Technology Management Reform Act, identifying standards and guidelines developed by the National Institute of Standards and Technology (NIST) for federal computing systems. NIST, NIST Special Publication 800–53, Rev 4, *Security and Privacy Controls for Federal Information Systems and Organizations* (April 2013), *http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf* (explaining specific security controls required by the Federal Information Security Management Act of 2002 and thereafter the Federal Information Security Modernization Act of 2014).

[101] Agencies must "evaluat[e] . . . whether (and if so, to what extent) the burden on respondents can be reduced by use of automated, electronic, mechanical, or other technological collection techniques or other forms of information

This consideration is particularly relevant to EEO–1 reporting. In the years since the EEOC first estimated the PRA burden of the EEO–1 based only on the time to fill in the cells on a paper EEO–1 report, there have been major advances in technology both for employers and the Joint Reporting Committee. Many employers now rely on HRIS and automated payroll systems.[102] The Joint Reporting Committee now utilizes an online EEO–1 portal for the confidential filing of EEO–1 reports, either by digital upload or by data entry onto a password-protected, partially pre-populated digital EEO–1.

Throughout the Joint Reporting Committee's transition to this new system, the EEOC continued to calculate the PRA burden based on its original method of counting all the cells on a paper report and calculating the time needed to enter data into each of them. However, with the 60-Day Notice, the EEOC concluded that both digital recordkeeping and digital filing were sufficiently well-established to transition to a new PRA methodology more suited to the new technology and the time-savings it generated.[103] The EEOC's new PRA methodology—necessarily expressed in the PRA's terms of hours and hourly labor rates—focuses on the time needed by the employer's staff to complete tasks such as reading the EEO–1 instructions, collecting, verifying, validating, certifying, and submitting the report. Therefore, in the 60-Day Notice, the EEOC considered for the first time the time savings generated by this task-based approach stemming from technology.[104] This is the reason that the burden of filing the EEO–1 actually declined with the PRA calculations in 60-Day Notice, relative to the paper-based calculation method previously used.

In the 60-Day Notice, the EEOC concluded that most employers would be filing the EEO–1 with a digital file upload by the time they file their EEO–1 reports for 2017 and 2018. Therefore, in the 60-Day Notice, the EEOC reasoned that "each additional report filed [would have] just a marginal additional cost." [105] Accordingly, the burden calculation in the 60-Day Notice was based on the number of *firms* filing one or more EEO–1 reports, not on the number of reports submitted or the number of separate establishments submitting reports. The EEOC's PRA burden calculations also assumed that all employees working on the EEO–1 would be administrative staff paid an hourly rate of $24.23 per hour.

The EEOC's intent in calculating respondent burden for the 60-Day Notice was to recognize the cost and time savings associated with the accelerating trend toward greater automation. However, employers' public comments indicated that the EEOC's estimates reflected a level of automation that was unlikely to be attained imminently. Some of these comments included estimates about the annual time and costs of completing the EEO–1. While some firms stated that they spent *less* time each year on the EEO–1 than the EEOC estimated in the 60-Day Notice, many firms reported that they spent *more* time and used more varied professional staff. These same commenters observed that they used data uploads less frequently than the EEOC had projected.

The EEOC carefully considered employers' input, yet, their comments as a whole reflected widely discrepant estimates of the time needed, jobs involved, and HRIS and software costs associated with digital EEO–1 reporting. Although the EEOC recognizes that the EEO–1 may involve more time than it estimated in the 60-Day Notice, the EEOC also concludes that the amount of time a filer spends each year completing this report varies, because each employer is different in terms of number of establishments, number of employees involved in producing the report, time spent by those employees and their rates of pay, and sophistication of HRIS. Due to the wide range of estimates provided about annual reporting costs, the EEOC also relied on its own experience collecting the EEO–1 reports and working with EEO–1 stakeholders over the years.

In conclusion, the EEOC adjusted its methodology for calculating PRA annual burden in this 30-Day Notice. First, the EEOC took into account the time and pay rates for a range of employees at both the firm- and establishment- levels who are responsible for preparing and filing the EEO–1. The EEOC now accounts for time to be spent annually on EEO–1 reporting by everyone from the executive who certifies it, to the lawyer who reviews it and the human resource professionals who prepare it with the support of information technology professionals and clericals.

Second, the EEOC no longer assumes that all the EEO–1 reports for 2017 and 2018 will be submitted by one data upload filed by the firm on behalf of all the establishments. While still reflecting that the bulk of the tasks performed in completing the EEO–1 report will be completed at the firm level due to the centrality of automation, the EEOC's 30-Day Notice recognizes that there are certain tasks that will be performed at the establishment level for employers who enter their EEO–1 data directly onto the Joint Reporting Committee's secure portal. Therefore, the 30-Day Notice burden calculations are based on the number of hours needed to complete the tasks at the firm level and also at the establishment level for the proportion of EEO–1 filers who do *not* now use centralized, secure data uploads. To make these calculations, the EEOC distinguished the time spent at the firm and establishment levels on the different types of EEO–1 reports, such as single-establishment Type 1 reports, Type 2 consolidated reports for employers with multiple establishments, and Type 6 or 8 reports for small establishments (under 50 employees).

For those employers who have staff enter EEO–1 data online, which is closest digital equivalent to completing a paper form by hand, the Joint Reporting Committee's password-protected, individualized portal prompts the employer with pre-populated EEO–1 forms that already include identifying information and the prior year totals. Moreover, the Joint Reporting Committee's online portal does not compel these employers to enter "zeros" in the cells for which they do not submit data. No EEO–1 filers enter data in every cell, so basing the annual PRA burden on the total number of cells on the EEO–1 form would be inaccurate.

Therefore, as explained in detail below, the total estimated *annual* burden hour cost in 2017 and 2018 for those contractors that will complete and submit only Component 1 (contractors with 50–99 employees) will be $1,872,792.41. The total estimated *annual* burden hour cost in 2017 and 2018 for employers and contractors that will complete both Components 1 and 2 will be $53,546,359.08.

The EEOC estimates that for these filers submitting both Component 1 and 2 data in 2017 and 2018, the *addition* of pay data will increase the estimated annual burden hour costs by a total of $25,364,064.80 or an average of $416.58 per EEO–1 filer each year, using the 30-Day PRA analysis. This is an average

---

technology, *e.g.*, permitting electronic submission of responses." 5 CFR 1320.8(a)(5).

[102] International Public Management Association for Human Resources, *Public Personnel Management*, Volume 39, No. 3, Fall 2010, *http://ipma-hr.org/files/pdf/ppm/ppmfall2010.pdf* (reporting that 90% of human resources departments used some form of HRIS).

[103] 81 FR 5113, 5120 (Feb. 1, 2016).

[104] *Id.*

[105] *Id.*

estimate per filer, and actual costs will vary, as explained in this Notice.

B. 60-Day Notice

In the 60-Day Notice, the EEOC estimated burden based on centralized electronic, rather than paper, filing of the EEO–1. Costs were calculated assuming that all tasks were performed at the firm level.

Burden Statement—2016: For reporting year 2016, when all filers will continue to submit only Component 1 demographic data, the EEOC estimated the total annual burden hours required to complete the EEO–1 as 228,296.4 hours, with an associated total annual burden hour cost of $5,531,621.77.

Burden Statement—Component 1 Only: The 60-Day Notice stated that starting in 2017, the estimated number of annual respondents (contractor filers) who will submit Component 1 only would be 6,260.[106] The 60-Day Notice estimated the burden in 2017 on contractor filers with 50 to 99 employees as follows:

- *Annual Burden Calculation:* The total annual burden hours required to complete Component 1 of the EEO–1 data collection in 2017 and 2018 was estimated to be 21,284 hours each year, with an associated total annual burden hour cost of $515,711.32. This figure used an average wage rate of $24.23 for employees working on the EEO–1, based on the conclusion that administrative support staff would perform the work in completing an EEO–1 report.

Burden Statement—Components 1 and 2: The 60-Day Notice estimated the number of annual respondents that would submit both Components 1 and 2 starting with the 2017 reporting cycle at 60,886 private industry and contractor filers. Filers required to complete both Components 1 and 2 were estimated to incur 401,847.6 burden hours annually or 6.6 hours per filer.

- *Annual Burden Calculation:* The estimated total annual burden hours needed for filers to report demographic and W–2 income and hours-worked data via Components 1 and 2 of the revised EEO–1 was estimated at 401,847.6, with an associated total annual burden hour cost of $9,736,767.35. This burden estimate includes reading instructions and collecting, merging, validating, and reporting the data electronically.[107]
- *One-Time Implementation Burden:* The estimated one-time implementation burden hour cost for submitting the information required by Component 2 of the revised EEO–1 Report was estimated as $23,000,295.[108] This calculation was based on the one-time cost for developing queries related to Component 2 in an existing human resources information system, which was estimated to take 8 hours per filer at a wage rate of $47.22 per hour.

The 60-Day Notice also estimated that the addition of W–2 income data to the EEO–1 would result in the EEOC incurring $318,000 in one-time costs and would raise the EEOC's recurring internal staffing cost by $290,478 due to the increased staff time needed to process the additional data.

C. 30-Day Notice

In response to concerns raised in the public comments to the 60-Day Notice, this 30-Day Notice reflects an increased burden estimate by: (1) Reflecting varying labor costs for the different types of staff involved with preparing the EEO–1, (2) adding labor costs for report-level functions, and (3) increasing the total number of burden hours a firm would need to read the EEO–1 instructions and to collect, verify, and enter EEO–1 data on the EEO–1 online portal. This methodology increases the total number of hours spent annually, even though the 30-Day Notice reduced overall burden by no longer requiring employers to make special W–2 income calculations for the EEO–1. This reflects employers' feedback about the annual EEO–1 reporting burden.

1. Annual Burden Hours

The 30-Day Notice revises the annual burden hour estimates to add the estimated time spent on firm-level functions by several different types of employees. These estimates are informed by the comments on the 60-Day Notice, based on the EEOC's experiences in providing technical assistance to employers, and within the range of time suggested by public comments.

To submit a report containing EEO–1 Component 1 data, the EEOC now assumes that, at the firm level, computer specialists would need to spend 4 hours, senior human resource managers, corporate legal counsel, and chief executive officers would each spend 1 hour, and data entry clerks and clerical staff would each spend 0.5 hours, for a total of 8 hours to complete firm-level functions.

Based on information received during the comment period, the addition of Component 2 data would increase the total time spent by each of these employees by a factor of 1.9. Therefore, the EEOC estimates that beginning with the 2017 EEO–1, each firm reporting both Component 1 and Component 2 data would require 7.6 hours by computer specialists, 1.9 hours each by senior human resource managers, corporate legal counsel, and chief executive officers, and 0.95 hours each by data entry clerks and clerical staff, for a total of 15.2 hours per firm for firm-level functions.

In order to analyze annual reporting burden as accurately as possible, the EEOC now also considers the time and effort associated with completing the different types of EEO–1 reports. There are six types of EEO–1 reports, as detailed in the footnote.[109] All reports except the Type 6 report include the requested EEO–1 workforce data; the Type 6 report includes only the employer's name, address, and the number of employees in each establishment with fewer than 50 employees. An employer having establishments with fewer than 50 employees chooses between filing one Type 6 report or multiple Type 8 reports (a full EEO–1 report for the establishment). If it chooses to file separate Type 8 reports for each establishment with fewer than 50 employees, the Joint Reporting Committee does not require it to complete a consolidated EEO–1 for the entire firm; rather, the Joint Reporting Committee's software generates a Type 2 report for the employer. However, if the employer chooses to submit a Type 6 report, it must also complete a full consolidated report. Accordingly, firms that have establishments with fewer than 50 employees either submit Type 8 reports (one for each establishment) or a Type 6 report (a list covering all establishments) plus a Type 2 report.

Finally, based on the EEOC's experience, most firms complete all the tasks associated with filing EEO–1 Type 1, 2, and 6 reports at the firm level. By contrast, for Type 3, 4 and 8 reports, some of the tasks are performed at the firm level, but others are performed at the establishment level. The EEOC's 30-Day Notice annual burden estimates therefore reflect time spent on establishment-level tasks associated with Type 3, 4, and 8 reports, while time spent on tasks associated with Type 1, 2, and 6 reports (and the firm-level functions associated with Types 3, 4, and 8) are included in the firm-level estimates.[110]

---

[106] 81 FR 5113 (Feb. 1, 2016). Of the 67,146 firms that filed EEO–1 reports in 2014, 6,260 were federal contractor filers with fewer than 100 employees.

[107] 81 FR 5113 (Feb. 1, 2016). This estimate was calculated as follows: 6.6 hours per respondent × 60,886 respondents = 401,847.6 hours × $24.23 per hour = $9,736,767.35. *See also* U.S. Dept. of Labor Bureau of Labor Statistics, *Employer Costs for Employee Compensation—December 2013* (March 2014), *http://www.bls.gov/news.release/archives/ecec_03122014.htm* (listing total compensation for administrative support as $24.23 per hour).

[108] 81 FR 5113 (Feb. 1, 2016). This estimate was calculated as follows: 8 hours per respondent × 60,886 employers = 487,088 × $47.22 per hour = $23,000,295. *See also* U.S. Dept. of Labor, Bureau of Labor Statistics, *Employer Costs for Employee Compensation—December 2013, supra* note 108 (listing total compensation for a professional as $47.22 per hour).

[109] Type 1 (single establishment firm); Type 2 (consolidated report for headquarters and multi-establishment firm); Type 3 (headquarters report); Type 4 (report for establishments with over 50 employees); Type 6 (list of establishments with under 50 employees); and Type 8 (detailed report for establishments with under 50 employees).

The EEOC assumes that human resource specialists and data entry clerks will perform all establishment-level functions. For firms filing only Component 1 of the EEO–1, the EEOC estimates that for each establishment report submitted, a human resource specialist and a data entry clerk would each spend 0.5 hours on establishment-level functions, for a total of 1 hour per report. Beginning in 2017, firms filing both Component 1 and Component 2 of the EEO–1 would require 0.95 hours each from the human resource specialist and the data entry clerk on establishment-level functions, for a total of 1.9 hours per report.

In 2014, 1,449 firms submitted their EEO–1 reports via data upload, but they submitted 329,944 Type 3, 4, and 8 reports.[111] The EEOC estimates that firms using data upload will need to spend less time at the establishment level than firms submitting their reports by data entry. For firms using data upload, the EEOC estimates that data entry clerks will not need to perform any establishment-level tasks.

2. Hourly Wage Rates

Using figures reflecting median pay obtained from the Bureau of Labor Statistics,[112] the EEOC's 30-Day Notice uses hourly wage rates as follows: Computer specialist $24.75, senior human resource manager $50.21, corporate legal counsel $55.69, chief executive officer $49.37, data entry clerk $13.69, clerical staff $15.41, and human resource specialist $28.06. See Table 3 for an illustration of the jobs, hours, and wage rates described in this Notice. Based on the EEOC's experience, the bulk of the work is now performed by computer specialists and senior human resource managers. At the establishment level, the EEOC concluded that EEO–1 reporting work is more likely to be performed by data entry clerks and human resource specialists, resulting in a lower average wage rate for establishment-level functions.

Table 3—EEO–1 Jobs, Hours, and Wages

Job title	Hours spent on EEO–1 Component 1 only	Hours spent on EEO–1 Components 1 & 2	Hourly wage rates
Firm-Level Functions			
Computer Specialist	4	7.6	$24.75
Senior Human Resource Manager	1	1.9	50.21
Corporate Legal Counsel	1	1.9	55.69
Chief Executive Officer	1	1.9	49.37
Data Entry Clerk	0.5	0.95	13.69
Clerical Staff	0.5	0.95	15.41
Report-Level Functions			
Human Resource Specialist	0.5	0.95	28.06
Data Entry Clerk	0.5	0.95	13.69

XII. Formal Paperwork Reduction Act Statement

A. Overview of Information Collection

The EEOC has submitted to OMB a request for a three-year PRA approval of a revised EEO–1. The revised EEO–1 data collection has two components. The first component (Component 1) will collect information identical to that collected by the currently approved EEO–1. The second component (Component 2) will collect data on employees' W–2 pay and hours worked. Component 1 can be found at *http://www.eeoc.gov/employers/eeo1survey/upload/eeo1-2.pdf.* An illustration of the data to be collected by both Components 1 and 2 can be found at *http://10.5.0.211/employers/eeo1survey/2016_new_survey.cfm.*

For the 2016 reporting cycle, there will be no change to the EEO–1 reporting requirement. All EEO–1 filers will continue to submit the data on race, ethnicity, sex, and job category that is currently collected by the EEO–1 report. The EEOC refers to this demographic and job category data as Component 1 data. Beginning with the 2017 reporting cycle, the EEOC proposes to require EEO–1 filers with 100 or more employees to submit data on pay and hours worked (Component 2 data) in addition to Component 1 data. However, federal contractor filers with 50 to 99 employees will only submit Component 1 data.

1. 2016 Overview of Information Collection—Component 1

Collection Title: Employer Information Report (EEO–1).

OMB Control Number: 3046–0007.

Frequency of Report: Annual.

Description of Affected Public: Private industry filers with 100 or more employees and federal government contractor filers with 50 or more employees.

Number of Respondents: 67,146 firms filing 683,275 establishment reports.

Reporting Hours: 1,055,471.

Respondent Burden Hour Cost: $30,055,086.62.

Federal Cost: $1,330,821.

Number of Forms: 1.

Form Number: EEOC Form 100.

---

[110] Because of this, the EEOC's burden estimates for firm-level tasks are inflated for those firms electing to file Type 8 reports, because the firm-level estimates include time spent completing a Type 2 and a Type 6 report, even though firms that opt to complete Type 8 reports do not also submit a Type 2 or Type 6 report.

[111] In 2014, contractor filers with 50–99 employees submitted 86 Type 3, 4, and 8 reports via data upload.

[112] U.S. Dept. of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook, http://www.bls.gov/ooh/.*

2. 2017 and 2018 Overview of Information Collection—Components 1 and 2

Collection Title: Employer Information Report (EEO–1).
OMB Control Number: 3046–0007.
Frequency of Report: Annual.
Number of Forms: 1.
Form Number: EEOC Form 100.
Federal Cost: $318,000 for one-time costs and $1,621,300[113] for recurring staffing costs.

a. Component 1 (Demographic and Job Category Data)

Description of Affected Public: In 2017 and 2018, contractor filers with 50 to 99 employees will submit only the demographic and job category data collected by Component 1.
Number of Respondents: 6,260 firms filing 9,129 establishment reports.
Reporting Hours: 59,166.
Respondent Burden Hour Cost: $1,872,792.41.

b. Components 1 and 2 (Demographic and Job Category Data Plus W–2 and Hours Worked Data)

Description of Affected Public: In 2017 and 2018, EEO–1 filers with 100 or more employees will submit pay and hours worked data under Component 2 in addition to demographic and job category data under Component 1.
Number of Respondents: 60,886 firms filing 674,146 establishment reports.
Reporting Hours: 1,892,979.5.
Respondent Burden Hour Cost: $53,546,359.08.

B. 30-Day Notice PRA Burden Statement

2016: Component 1

Burden Statement: In 2016, all EEO–1 filers will submit Component 1, which only includes the data collected by the currently approved EEO–1. No filer will be required to submit the Component 2 data during the 2016 reporting cycle. The estimated number of respondents required to submit the annual EEO–1 report is 67,146.[114] This data collection is estimated to impose 1,055,471 burden hours in 2016 or 8 hours per filer for firm-level functions plus an additional one hour per report for establishment-level functions.[115] The associated burden hour cost for the 2016 reporting cycle is $30,055,086.62.[116] This estimate assumes electronic filing through the EEO–1 online portal either by data entry or data upload, and accounts for time and cost savings now associated with submission of the EEO–1 via data upload.

2017 and 2018: Components 1 and 2

With respect to the EEO–1 reporting cycles for 2017 and 2018, this Notice will discuss the burden estimates associated with two distinct groups of filers. The first group consists of contractor filers with 50 to 99 employees. This group of filers will continue to submit only the Component 1 data, just as they have done in previous years. The second group of filers includes all EEO–1 filers with 100 or more employees, whether private industry or contractor filers. This larger group will continue to submit Component 1 data as they have always done, but will also submit the newly-added W–2 and hours-worked data of Component 2.

Burden Statement—Component 1 Only: Starting in 2017, the estimated number of annual respondents who are contractor filers with 50 to 99 employees is 6,260.[117] Again, this calculation assumes 8 hours per filer for firm-level functions plus an additional one hour per individual report for report-level functions. The burden on these contractor filers is estimated as follows:

- *Annual Burden Calculation:* The estimated total annual burden hours required to complete Component 1 of the EEO–1 data collection in 2017 and 2018 is 59,166,[118] with an associated total annual burden hour cost of $1,872,792.41.[119]

Burden Statement—Components 1 and 2: Starting in 2017, the estimated number of annual respondents that will submit Components 1 and 2 is 60,886 private industry and contractor filers. Filers required to complete both Components 1 and 2 are estimated annually to incur a total of 15.2 hours per filer for firm-level functions plus an additional 1.9 hours per individual report for establishment-level functions. The estimated burden is based on electronic filing.

The burden imposed on all private industry employer filers and contractor filers with 100 or more employees as a result of the proposed collection of Component 1 and 2 data is estimated as follows:

- *Annual Burden Calculation:* The estimated total annual burden hours needed for all filers required to report Components 1 and 2 data is 1,892,979.5 hours,[120] with an associated total annual burden hour cost of $53,546,359.08.[121] The EEOC estimates that for these filers submitting both Component 1 and 2 data in 2017 and 2018, the *addition* of pay data will increase the estimated annual burden hour costs by a total of $25,364,064.80 or an average of $416.58 per EEO–1 filer each year. This burden estimate includes reading instructions and collecting, merging, validating, and reporting the data electronically.

---

[113] The addition of W–2 pay data to the EEO–1 is expected to increase EEOC's internal staffing costs by approximately $290,478. The annual federal cost figure of $1,621,300 includes both the increase in contract costs resulting from the addition of the pay data collection and the estimated internal staffing costs. It reflects an increase of more than $290,478 compared to the estimated federal costs provided in previously published **Federal Register** notices seeking PRA approval of this information collection because past estimates reflected the cost of the contract with the vendor whose services the EEOC procures to assist with administration and processing of the EEO–1 but did not include EEOC's internal staffing costs associated with processing the EEO–1.

[114] In 2014, 67,146 firms filed EEO–1 reports.

[115] This estimate calculates total time spent by firms assuming no data upload, then subtracts the estimated time saved by firms using data upload, as follows: 8 hours per firm for firm-level functions × 67,146 firms = 537,168 hours; 1 hour per report for establishment-level functions × 683,275 reports = 683,275 hours; 537,168 + 683,275 = 1,220,443 total hours; 0.5 hours per report of data entry clerk time saved by data upload × 329,944 reports filed by data upload = 164,972; 1,220,443 − 164,972 = 1,055,471.

[116] To reach this estimate, the EEOC multiplied the hourly wage rates for each job by the estimated hours spent by each job in completing the EEO–1 to arrive at a per-firm cost for firm-level functions of $268.82 and a per-report cost for establishment-level functions of approximately $20.88 (rounded). The total burden hour cost for firm-level functions is $18,050,187.7 and the total burden hour cost for establishment-level functions is $14,263,365.6. Firms using data upload are estimated to save $2,258,466.68 (data entry clerk hourly wage rate of $13.69 × 0.5 hours × 329,944 reports filed by data upload). Total firm-level burden hour cost of $18,050,187.7 + total establishment-level burden hour cost of $14,263,365.6 − cost savings from data upload of $2,258,466.68 = a total annual burden hour cost of $30,055,086.62.

[117] Of the 67,146 firms that filed EEO–1 reports in 2014, 6,260 were federal contractor filers with fewer than 100 employees.

[118] This estimate calculates total time spent by firms assuming no data upload, then subtracts the estimated time saved by firms using data upload, as follows: 8 hours per firm for firm-level functions × 6,260 firms = 50,080 hours; 1 hour per report for establishment-level functions × 9,129 reports = 9,129 hours; 50,080 + 9,129 = 59,209 total hours; 0.5 hours per report of data entry clerk time saved by data upload × 86 reports filed by data upload = 43; 59,209 − 43 = 59,166.

[119] To reach this estimate, the EEOC multiplied the adjusted hourly rates for each job by the estimated hours spent by each job in completing the report to arrive at a per-firm cost for firm-level functions of $268.82 and a per-report cost for establishment-level functions of approximately $20.88 (rounded). The burden hour cost for firm-level functions is $1,682,813.2 and the burden hour cost for establishment-level functions is $190,567.875. Firms using data upload are estimated to save $588.67 (data entry clerk hourly wage rate of $13.69 × 0.5 hours × 86 reports filed by data upload). Total firm-level burden hour cost of $1,682,813.2 + total establishment-level burden hour cost of $190,567.875 − cost savings from data upload of $588.67 = a total annual burden hour cost of $1,872,792.41.

[120] This estimate calculates total time spent by firms assuming no data upload, then subtracts the estimated time saved by firms using data upload, as follows: 15.2 hours per firm for firm-level functions × 60,886 firms = 925,467.2 hours; 1.9 hours per report for establishment-level functions × 674,146 reports = 1,280,877.4 hours; 925,467.2 + 1,280,877.4 = 2,206,344.6 total hours; 0.95 hours per report of data entry clerk time saved by data upload × 329,858 reports filed by data upload = 313,365.1; 2,206,344.6 − 313,365.1 = 1,892,979.5.

[121] To reach this estimate, the EEOC multiplied the adjusted hourly rates for each job by the

- *One-Time Implementation Burden:* The 60-Day Notice estimated the one-time implementation burden hour cost associated with submitting the information required by Component 2 of the revised EEO–1 Report to be $23,000,295. This was based on the one-time cost for developing queries related to Component 2 in an existing HRIS, which was estimated to take 8 hours per filer at a wage rate of $47.22 per hour.

Employers filing public comments stated that bridging pay and HRIS systems, or purchasing software updates from vendors, would be extremely expensive. Some of these employers estimated the one-time implementation cost of bridging HRIS and payroll records to report Component 2 data estimated costs could range from $5,000 per firm to $20,000, $30,000, or $40,000 per firm. Although the estimates did not provide details explaining how *they* were calculated, the EEOC has considered this feedback and increased the one-time implementation burden. It has done so by reflecting that specialized computer software experts with a higher wage rate will be required to do the work necessary to implement the one-time changes required for this proposal.

Using an hourly wage rate for a computer programmer of $55.81, the EEOC now estimates one-time burden hour cost of $27,184,381.28.[122]

Dated: July 11, 2016.

For the Commission.

Jenny R. Yang,

Chair.

[FR Doc. 2016–16692 Filed 7–13–16; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, July 14, 2016

July 7, 2016.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, July 14, 2016 which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item No.	Bureau	Subject
1	Wireless Tele-Commucations, International And Office Of Engineering & Technology.	Title: Use of Spectrum Bands Above 24 GHz For Mobile Radio Services (GN Docket No. 14–177); Establishing a More Flexible Framework to Facilitate Satellite Operations in the 27.5–28.35 GHz and 37.5–40 GHz Bands (IB Docket No. 15–256); Petition document of the Fixed Wireless Communications Coalition to Create Service Rules for the 42–43.5 GHz Band (RM–11664); Amendment of Parts 1, 22, 24, 27, 74, 80, 90, 95, and 101 To Establish Uniform License Renewal, Discontinuance of Operation, and Geographic Partitioning and Spectrum Disaggregation Rules and Policies for Certain Wireless Radio Services (WT Docket No. 10–112); Allocation and Designation of Spectrum for Fixed-Satellite Services in the 37.5–38.5 GHz, 40.5–41.5 GHz and 48.2–50.2 GHz Frequency Bands; Allocation of Spectrum to Upgrade Fixed and Mobile Allocations in the 40.5–42.5 GHz Frequency Band; Allocation of Spectrum in the 46.9–47.0 GHz Frequency Band for Wireless Services; and Allocation of Spectrum in the 37.0–38.0 GHz and 40.0–40.5 GHz for Government Operations (IB Docket No. 97–95). Summary: The Commission will consider a document that would make spectrum in bands above 24 GHz available for flexible use wireless services, including for next-generation, or 5G, networks and technologies.
2	Wireline Competition	Title: Technology Transitions (GN Docket No. 13–5); USTelecom Petition for Declaratory Ruling that Incumbent Local Exchange Carriers Are Non-Dominant in the Provision of Switched Access Services (WC Docket No. 13–3); Policies and Rules Governing Retirement of Copper Loops by Incumbent Local Exchange Carriers (RM–11358). Summary: The Commission will consider a document that adopts a framework to guide transitions to next-generation communications technologies while protecting the interests of consumers and competition.

---

estimated hours spent by each job in completing the report to arrive at a per-firm cost for firm-level functions of approximately $510.76 and a per-report cost for establishment-level functions of approximately $39.66 (these figures are rounded). The burden hour cost for firm-level functions is $31,098,011.6 and the burden hour cost for establishment-level functions is $26,738,315.7. Firms using data upload are estimated to save $4,289,968.22 (data entry clerk hourly wage rate of $13.69 × 0.95 hours × 329,858 reports filed by data upload). Total firm-level burden hour cost of $31,098,011.6 + total establishment-level burden hour cost of $26,738,315.7 − cost savings from data upload of $4,289,968.22 = a total annual burden hour cost of $53,546,359.08.

[122] This estimate is calculated as follows: 8 hours per respondent × 60,886 employers = 487,088 × $55.81 per hour = $27,184,381.28. The higher one-time implementation burden estimate in this Notice as compared to the one-time implementation burden estimate in the 60-Day Notice is due to the higher wage rate for the computer programmer, multiplied by 1.46, which is the employer contribution for "management, professional, related." U.S. Dept. of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook: Computer Programmers, http://www.bls.gov/ooh/computer-and-information-technology/computer-programmers.htm; see also* U.S. Dept. of Labor, Bureau of Labor Statistics, *Employer Costs for Employee Compensation—Dec. 2015* (Mar. 2016), *http://www.bls.gov/news.release/archives/ecec_03102016.htm* (computing the rate of employer contribution by dividing total compensation by total salary).

* * * * *

Consent Agenda

The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:

1	General Counsel	Title: William J. Kirsch Request for Inspection of Records (FOIA Control No. 2015–368). Summary: The Commission will consider a Memorandum Opinion and Order concerning the application for review filed by William J. Kirsch regarding a decision of the International Bureau's fee estimate for processing his Freedom of Information Act (FOIA) request.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–16620 Filed 7–13–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, June 28, 2016 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

Federal Register notice of previous announcement—81 FR 40888.

Change in the Meeting: This meeting was continued on July 12, 2016.

Person to Contact for Information: Judith Ingram, Press Officer; Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary.

[FR Doc. 2016–16805 Filed 7–12–16; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL TRADE COMMISSION

[File No. 151 0088]

Ball Corporation and Rexam PLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before July 28, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/ballrexamconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "In the Matter of Ball Corporation and Rexam PLC, File No. 151 0088—Consent Agreement" on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/ballrexamconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Ball Corporation and Rexam PLC, File No. 151 0088—Consent Agreement" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael Lovinger (202–326–2539), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 28, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before July 28, 2016. Write "In the Matter of Ball Corporation and Rexam PLC, File No. 151 0088—Consent Agreement" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/ballrexamconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write "In the Matter of Ball Corporation and Rexam PLC, File No. 151 0088—Consent Agreement" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 28, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order To Aid Public Comment

I. Introduction and Background

Pursuant to an agreement dated February 19, 2015 (the "Acquisition"), Ball Corporation ("Ball") seeks to acquire Rexam PLC ("Rexam") in a transaction valued at approximately £5.4 billion, or $8.4 billion, at the time the Acquisition was announced. In order to preserve competition that would be lessened as a result of the proposed Acquisition, the Federal Trade Commission ("Commission") has accepted for public comment, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Ball and Rexam. The Commission has also issued a Complaint and Decision & Order, and has assigned a Monitor Trustee to oversee compliance with the Consent Agreement.

The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the markets for standard 12-ounce aluminum beverage cans ("Standard Cans") and specialty aluminum beverage cans ("Specialty Cans") in the United States. The Consent Agreement would remedy the alleged violations by restoring the competition that would be lost as a result of the proposed Acquisition.

Under the terms of the proposed Consent Agreement, Ball and Rexam are required to divest seven aluminum can body plants, one aluminum can end plant, and other innovation and support functions in order to preserve competition in the relevant markets in the United States. These manufacturing plants account for the majority of Rexam's sales in the United States. Ball and Rexam have agreed to divest these and additional assets around the world to Ardagh Group S.A. ("Ardagh") in a transaction entered into on April 22, 2016 and valued at $3.42 billion, including assumption of liabilities.

The proposed Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed Consent Agreement and any comments received, and decide whether the Consent Agreement should be withdrawn, modified, or made final.

II. The Parties

Ball, an Indiana corporation headquartered in Broomfield, CO, is the largest manufacturer of aluminum beverage cans in the both the United States and the world. In 2015, Ball had total sales of $8.0 billion, 74% of which were derived from its worldwide metal beverage container business. Approximately 16% of Ball's revenues come from its worldwide sales of metal food and household containers, and approximately 10% from its U.S. aerospace business. In 2015, Ball had approximately $2.7 billion in sales of aluminum beverage cans in the United States.

Rexam is the second-largest manufacturer of aluminum beverage cans in North America and the world. Rexam is a United Kingdom company headquartered in London. Rexam manufactures only aluminum beverage containers today, after selling its plastic packaging business in 2011 and its glass manufacturing business in 2005. In 2015, Rexam had total aluminum beverage container sales of about $5.7 billion, with approximately $1.75 billion coming from the United States.

Ardagh, headquartered in Luxembourg, is one of the world's largest producers of glass bottles for the beverage industry and metal cans for the food industry. Ardagh does not currently produce aluminum cans for the beverage industry, but it serves many of the same customers as Ball and Rexam through its glass bottle business. In 2015, Ardagh had sales of approximately $5.9 billion, with approximately $3.6 billion coming from glass packaging and $2.3 billion from metal food packaging.

III. Standard Cans

The first relevant line of commerce in which to analyze the Acquisition is standard 12-ounce aluminum beverage cans ("Standard Cans"). Approximately 3 out of every 4 beverage cans sold in the United States today are Standard Cans, which are found, for instance, in a 12-pack of carbonated soft drinks or beer. Beverage producers purchase Standard Cans because of their superior shelf life, filling efficiency, recyclability, compact storage, and relatively low cost.

---

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Other packaging substrates, such as plastic bottles and glass bottles, do not serve as competitive constraints to Standard Cans. Beverage producers sell their products in different types of containers in order to meet consumer demand, and could not substitute other container types for Standard Cans without risking a loss in sales. Beverage producers have also invested substantial sums of money in specialized filling lines that are designed to fill either aluminum cans, plastic bottles, or glass bottles, and cannot switch from one container type to another. As a result, beverage producers negotiate for Standard Cans independently from plastic bottles and glass bottles, and do not shift volumes between Standard Cans and other packaging substrates in response to fluctuations in their relative prices.

The relevant geographic markets in which to analyze competition for Standard Cans are regional. Beverage producers incur significant freight costs from shipping empty cans to their filling plants. For this reason, manufacturers of Standard Cans have built a network of plants throughout the United States to meet regional customer demand and minimize shipping costs. Although aluminum can manufacturers often ship Standard Cans several hundred miles and win bids when they are not the closest supplier, it is not common or cost-effective for Standard Cans to ship cross-country. As a result, the Complaint identifies three regional markets in the United States in which substantial competition exists between Ball and Rexam for the sale of Standard Cans: (1) The South/Southeast; (2) the Midwest; and (3) the West Coast, consisting primarily of California.

The Commission often calculates the Herfindahl-Hirschman Index ("HHI") to assess market concentration. Under the Federal Trade Commission and Department of Justice Horizontal Merger Guidelines, markets with an HHI above 2,500 are generally classified as "highly concentrated," and acquisitions "resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market power."[2] Absent the proposed remedy, the Acquisition would increase HHIs for Standard Cans by 1,712 points to 4,874 in the South/Southeast; by 2,201 points to 5,050 in the Midwest; and by 1,673 points to 4,680 on the West Coast. As a result, there is a presumption that the proposed merger of Ball and Rexam would substantially lessen competition in each of the regional markets for Standard Cans.

IV. Specialty Cans

The second relevant line of commerce in which to analyze the Acquisition is an assortment of specialty aluminum beverage cans ("Specialty Cans"), which come in a variety of dimensions that differ from Standard Cans. Specialty Cans include 7.5-ounce and 8-ounce slim cans, which are narrower and shorter than Standard Cans; 12-ounce sleek cans, which are narrower and taller than standard 12-ounce cans; 16-ounce cans, which have the same diameter as Standard Cans but are taller; 24-ounce cans, which are wider and taller than Standard Cans; and other aluminum cans in non-standard shapes and sizes. Specialty Can sales have been growing as beverage producers seek to package their products in new shapes and sizes to reach different consumers and consumption occasions.

Beverage producers package in different types of Specialty Cans for different reasons. For example, carbonated soft drink producers package some of their products in 7.5-ounce slim cans specifically to reach consumers who want a smaller portion in an attractive, sub-100 calorie package. Popular with producers of flavored malt beverages are 8-ounce slim cans. Energy drink producers package in 16-ounce and other "sleek" cans in order to differentiate their products and convey a premium image in ways that cannot be achieved by using Standard Cans. Some tea and energy drink producers further differentiate their products and convey value by packaging in large 24-ounce cans.

Although one type of Specialty Can is not typically a substitute for another, it is appropriate to group or cluster the different Specialty Cans together for the purposes of market definition analysis because each of the products in the assortment is offered under similar competitive conditions. As such, grouping the many different types of Specialty Cans into a single cluster enables a more efficient evaluation of competitive effects.

Beverage producers would not substitute Standard Cans, glass bottles, plastic bottles, or other container types for Specialty Cans in sufficient quantities to defeat a hypothetical, small but significant and non-transitory increase in the price of Specialty Cans. Beverage producers package in specific shapes and sizes of Specialty Cans to maximize sales and attract certain customers who would not purchase their products in a different package type. Moreover, beverage producers have made substantial investments in infrastructure that are used to fill Specialty Cans and that cannot be used to fill PET bottles or glass bottles.

The relevant geographic market in which to analyze Specialty Cans is the United States. A national market is appropriate because each Specialty Can type is produced at only a small number of locations nationwide, and Specialty Cans are shipped over much longer distances than Standard Cans, often over 1,000 miles. Specialty Cans of particular shapes and sizes are produced at only a few locations in the United States because their volumes are only a small fraction of the volume of Standard Cans, and it is not cost-effective to spread such small volumes across a large number of plants.

Ball and Rexam are the two largest suppliers of Specialty Cans in the United States with shares of approximately 56% and 21%, respectively, across all Specialty Can sizes. Absent the proposed remedy, the Acquisition would increase HHIs for Specialty Cans by 2,284 points to 6,267 in the United States. As a result, there is a presumption that the proposed merger of Ball and Rexam would substantially lessen competition in the national market for Specialty Cans.

V. Effects of the Acquisition

Absent relief, the Acquisition would likely cause significant competitive harm in the markets for the manufacture and sale of Standard Cans and Specialty Cans to beverage producers. The Acquisition would eliminate substantial direct competition between Ball and Rexam for the sale of Standard Cans and Specialty Cans. In individual contract negotiations with Ball and Rexam, beverage producers have been able to secure better prices and other terms by switching, or threatening to switch, their business from one supplier to the other. In some of these negotiations, no other suppliers besides Ball and Rexam have submitted a bid, and beverage producers have therefore depended on the competition between Ball and Rexam to obtain a contract with favorable terms. The Acquisition would also increase the ease and likelihood of anticompetitive coordination between the only two remaining independent beverage can suppliers, Ball and Crown Holdings, Inc. Thus, the Acquisition would likely result in higher prices and a reduction in quality, selection, service, and innovation.

---

[2] 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines § 5.3.

VI. Entry

Entry in the manufacture of Standard Cans and Specialty Cans would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely competitive harm from the Acquisition. Considerable entry barriers exist in the manufacture of Standard Cans and Specialty Cans, including, but not limited to, substantial capital costs needed to construct a new aluminum can plant and significant volume requirements necessary to run a plant efficiently. For Standard Cans, a consistent decline in demand has created a further disincentive to entry, which has led to a steady removal of capacity for over 20 years. With respect to Specialty Cans, a new entrant would be at a significant disadvantage if it were to construct new Specialty Can lines compared to incumbent suppliers (led by Ball and Rexam) that can convert Standard Can lines to Specialty Can production at lower cost.

The threat of vertical integration by beverage producers is also unlikely to deter or counteract the competitive harm from the Acquisition. A single beverage can plant requires an annual production volume in the billions of cans to run profitably, which would preclude all but the very largest beverage producers from contemplating vertical integration. Moreover, it is difficult for even the largest beverage producers to make a credible threat of vertical integration because their filling plants are spread throughout the United States in a way that they could never fully supply internally. As a result, even a large, vertically integrated beverage producer would have to continue buying at least some beverage cans from existing suppliers, but at a higher price since it would receive a smaller volume discount, which would further disincentivize vertical integration. Coupled with the significant capital costs and technical requirements needed to build a new beverage can plant, vertical integration would not be a credible threat for the vast majority of beverage producers.

VII. The Proposed Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the Acquisition by requiring Ball to divest seven beverage can plants and one can end plant in the United States to Ardagh. Divestitures of Rexam's Bishopville, SC and Olive Branch, MS can plants preserve competition for Standard Cans in the South/Southeastern United States. Divestitures of Rexam's Fremont, OH and Chicago, IL can plants preserve competition for Standard Cans in the Midwest. Divestiture of Rexam's Fairfield, CA can plant preserves competition for Standard Cans on the West Coast. Divestitures of Rexam's Winston-Salem, NC, Whitehouse, OH, and Chicago, IL can plants preserve competition in Specialty Cans in the United States. Finally, divestiture of Rexam's Valparaiso, IN can end plant ensures that Ardagh will be able to manufacture lids for all of its Standard Cans and Specialty Cans produced in the United States.

As part of the Consent Agreement, Ball is also divesting Rexam's U.S. headquarters in Chicago, IL and Rexam's U.S. Technical Center in Elk Grove, IL to Ardagh. In addition, Ball has agreed to sell to Ardagh ten beverage can plants and two can end plants in Europe; two beverage can plants in Brazil; and other innovation and support functions in Germany, the United Kingdom, and Switzerland to resolve competitive concerns in Europe. Divestiture of the Ball and Rexam assets to a single, global buyer is important to preserve competition for many multinational customers.

The Consent Agreement requires Ball to transfer all customer contracts currently serviced at the beverage can plants that are being divested to Ardagh. Additionally, in order to fully service the customer contract with Arizona Beverage Co. ("Arizona") and to ensure the viability of certain divestiture assets, the Consent Agreement requires Ball to purchase a supply of beverage cans sufficient to service Arizona's requirements for the remaining duration of that agreement or until Ardagh enters into a separate customer agreement with Arizona.

The Consent Agreement also requires Ball to provide support services for up to 18 months, including support for potential line conversions from Standard Cans to Specialty Cans, at Ardagh's request. In addition, Ball must provide Ardagh with a royalty-free, perpetual license to use patents and technologies necessary to operate the divested can business. Ball and Rexam must also help facilitate the employment of certain key employees by Ardagh.

The Consent Agreement incorporates a proposed Order to Maintain Assets to ensure the continued health and competitiveness of the divested assets. The Consent Agreement also provides that the Commission may appoint a Monitor Trustee to monitor Ball and Rexam's compliance with their obligations pursuant to the Consent Agreement, and oversee the integration of the Rexam and Ball assets into Ardagh. The Commission has selected ING to serve as Monitor Trustee in this matter until integration of the divested assets is completed. The European Commission has also selected ING to oversee the divestiture, which makes the Monitor Trustee uniquely capable of monitoring the global transition of all assets acquired by Ardagh. The Consent Agreement also provides for appointment of a Divestiture Trustee to effectuate the divestitures if Ball fails to carry out the sale of assets and its related obligations.

Through the proposed divestitures, Ardagh will become the third-largest beverage can manufacturer in the United States and the world. Ardagh will own beverage can plants that span a broad geographic footprint, offer a well-balanced product mix, and have flexible manufacturing capabilities. Ardagh is an ideal buyer of the divested assets because it has existing long-standing relationships with key beverage customers through its glass bottle business, and existing experience with metal container manufacturing through its food can business. Furthermore, the fact that Ardagh does not currently produce aluminum beverage cans means that the divestiture will not create competitive issues of its own. Accordingly, Ardagh's acquisition of the divested assets will preserve the competition that would have otherwise been lost through Ball's acquisition of Rexam.

* * * * *

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–16687 Filed 7–13–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0114; Docket 2016–0053; Sequence 23]

Submission for OMB Review; Right of First Refusal of Employment

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection.

DATES: Submit comments on or before August 15, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0114, Right of First Refusal of Employment". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0114, Right of First Refusal of Employment" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Divison (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0114, Right of First Refusal of Employment.

Instructions: Please submit comments only and cite Information Collection 9000–0114, Right of First Refusal of Employment, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, at 202–208–4949 or via email at *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

As prescribed in FAR 7.305(c), the clause at FAR 52.207–3, Right of First Refusal of Employment, deals with adversely affected or separated Government employees resulting from the conversion of work from in-house performance to performance by contract. The clause requires the contractor to give these employees an opportunity to work for the contractor who is awarded the contract.

The information gathered will be used by the Government to gain knowledge of which employees, adversely affected or separated as a result of the contract award, have gained employment with the contractor within 90 days after contract performance begins. A notice was published in the **Federal Register** at 81 FR 19606 on April 5, 2016. No comments were received.

B. Annual Reporting Burden

Number of Respondents: 10.
Responses per Respondent: 1.
Total Responses: 10.
Hours per Response: 3.
Total Burden Hours: 30.
Frequency of Collection: On occasion.
Affected Public: Businesses or other for-profit and not-for profit organizations.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0114, Right of First Refusal of Employment, in all correspondence.

Dated: July 11, 2016.

Kathlyn Hopkins,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–16685 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data for Systematic Reviews Request on Osteoarthritis of the Knee: An Update

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Supplemental datasets are being solicited to inform the review of *Osteoarthritis of the Knee: An Update,* which is currently being conducted by AHRQ's Evidence-based Practice Centers (EPC) Programs. Obtaining access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before August 15, 2016.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: SEADS Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: SEADS Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 51723 or Email: *SEADS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned its Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence a review that updates information on treatments for osteoarthritis of the knee. The review will be titled *Osteoarthritis of the Knee: An Update.*

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, AHRQ is supplementing the usual manual and electronic database searches of the literature by requesting information (*e.g.*, details of studies conducted) from the public. We are looking for studies that report on treatments for osteoarthritis of the knee, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://www.effective healthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2247.*

This notice is to notify the public that the EPC program would find the following information on treatments for osteoarthritis of the knee helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute all Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or could be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program.

This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: *https://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2247*

Key Questions

Key Question 1

I. What is the clinical effectiveness of oral glucosamine and/or chondroitin, physical treatments, weight loss, oral serotonin-norepinephrine reuptake inhibitors (SNRIs), intraarticular corticosteroids and/or prolotherapy, topical or transdermal analgesics, acupuncture, or cell-based therapies in patients with primary or secondary OA of the knee, compared with appropriate placebo/sham controls or compared with other active interventions?

II. How do the outcomes of each intervention differ by the following population and study characteristics: Sex, disease subtype (lateral, patellofemoral), severity (stage/baseline pain and functional status), weight status (body mass index), baseline fitness (activity level), comorbidities, prior or concurrent treatments (including self-initiated therapies), and treatment duration or intensity?

Key Question 2

I. What harms are associated with each intervention in patients with primary or secondary OA of the knee?

II. How do the harms associated with each intervention differ by the following population or study characteristics: Sex, disease subtype (lateral tibiofemoral, patellofemoral), severity (stage/baseline pain and functional status), weight status (body mass index), baseline fitness (activity level), comorbidities, prior or concurrent treatments (including self-initiated therapies), and treatment duration or intensity?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Population(s)

I. Adults (age 18 or over) with a diagnosis of primary (or secondary) OA of the knee, as defined by the American Academy of Orthopaedic Surgeons (AAOS, 2013), ACR clinical classification criteria, or Kellgren-Lawrence stage.

II. Subpopulations of interest include those defined by sex, disease subtype (*e.g.*, patellofemoral, or medial tibiofemoral), disease severity (stage/pain or functional status), body mass index, fitness/activity level, prior treatment, concurrent treatment(s), comorbidities

III. Exclusions:

A. Studies of individuals under age 18; those with OA caused by a congenital condition; and those with OA concomitant with a meniscal or anterior cruciate ligament tear will be excluded because these participants have conditions that differ importantly from the vast majority of OA patients

B. Studies that include those who have had knee replacement surgery on the affected limb or for whom outcomes will be measured after knee replacement surgery or who have concomitant joint disease such as rheumatoid arthritis or gout will be excluded because these conditions or procedures will confound assessment of the outcomes of interventions.

C. If three or more RCTs of a particular intervention are included that enroll at least 50 participants per study arm, smaller studies of the same intervention will be excluded unless they report on a subgroup analysis of interest because studies on management of OA of the knee that enroll fewer than 50 participants per study arm have been shown to have high risk of bias and significantly larger effect sizes.

Interventions

I. Pharmacologic treatments
  A. Oral agents
    i. Glucosamine and/or chondroitin
    ii. SNRIs (to be assessed for review in next update)
  B. Intra-articular injected agents (to be assessed for review in next update)
    i. Corticosteroids (to be assessed for review in next update)
    ii. Prolotherapeutic agents (*e.g.* dextrose) (to be reviewed in next update)

iii. Hyaluronic acid (to be assessed for review in next update)
C. Topical and transdermal agents (to be assessed for review in next update)
i. Capsaicin (to be assessed for review in next update)
ii. NSAIDs (to be assessed for review in next update)
II. Cell-based therapies
A. Platelet-rich plasma
B. Intraarticular or arthroscopic administration of mesenchymal stem-cells or chondrocytes or tissue
C. Exclusions:
i. Phase I or II trials will not be included for efficacy, as the interventions are generally not FDA-approved for use.
III. Physical treatments and/or weight loss
A. Physical therapy and exercise programs
i. Manual therapy
ii. Land-based therapy and/or exercise
iii. Exercise programs (aerobic, resistance)
iv. Aquatherapy
v. Balneotherapy, mud therapy
vi. Heat or cold
vii. Self-management programs
B. Weight loss
C. Braces or kinesiology taping
D. Orthotic shoe inserts and/or wedges
E. Vibrating platform
F. Neuromuscular electrical stimulation (*e.g.,* Transcutaneous electrical nerve stimulation)
IV. Acupuncture (to be assessed for review in next update)
A. Needle acupuncture alone (to be assessed for review in next update)
B. Moxibustion (to be assessed for review in next update)
V. Combination interventions (to be assessed for review in next update)
A. Sequential treatment algorithms (to be assessed for review in next update)

Comparators

I. Pharmacologic treatments: Placebo-controlled or head-to-head non-inferiority only
II. Cell-based therapies: Placebo- or sham-controlled only
III. Physical treatments and/or weight loss: Placebo-controlled, usual care-controlled, or wait list-controlled only except for weight loss
IV. Neuromuscular electrical stimulation: Sham stimulation without current
V. Wait list
VI. Treatment as usual
VII. Studies that use the untreated knee as a control will be excluded, based on evidence indicating that individuals with OA in one knee are likely to have some, but not necessarily identically, reduced function in the other knee and that treatment of one knee only may improve pain in that knee but may not markedly improve function
VIII. Studies that use participants as their own controls will be excluded, unless no randomized controlled trials are identified for a particular intervention of interest, as quasi-experimental designs provide weaker evidence.
IX. Exclusions:
A. Studies that use an active control that has not been established to be effective will be excluded. Efficacy and effectiveness must be established before examining comparative effectiveness questions.

Outcomes

I. Short-term clinical outcomes
A. Pain (*e.g.,* VAS, WOMAC, KOOS,)
B. Joint stiffness (WOMAC)
C. Function (WOMAC, Lequesne, others)
D. OARSI physical outcomes (*e.g.,* timed up-and-go, 6-minute walk test)
E. Patient Reported Outcome Measurement System (PROMIS®) and Osteoarthritis-Computer Adaptive Test (OA–CAT)
F. Inflammation or effusion
G. Medication use
II. Long-term clinical outcomes
A. Any of the short-term clinical outcomes
B. Instrumental activities of daily living (IADLs)
C. Quality of life (*e.g.,* SF–36, EuroQuol EQ–5D, Arthritis Self-Efficacy scale, global assessment, patient satisfaction)
D. Surgery (*i.e.,* rate of undergoing knee replacement)
III. Adverse effects of intervention(s)
IV. Outcome reporting
A. Only studies that report outcomes for knee OA alone
B. Mean differences at followup or percent of responders at followup will be abstracted

Timing

Minimum 1 month follow-up from initiation of treatment

Settings

Any setting

Andrew B. Bindman,
AHRQ Director.

[FR Doc. 2016–16632 Filed 7–13–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH), Safety and Occupational Health Study Section: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Safety and Occupational Health Study Section, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through June 30, 2018.

For more information contact: JoAnne Fairbanks, Executive Secretary, Safety and Occupational Health Study Section, Department of Health and Human Services, 1600 Clifton Road NE., Mailstop E74, Atlanta, Georgia 30333, telephone 304/285–6143 or fax 304/285–6147.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,
Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–16583 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH), Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates: 8:15 a.m.–5:00 p.m., Mountain Time, August 9, 2016; 8:15 a.m.–1:00 p.m., Mountain Time, August 10, 2016.

Public Comment Time and Date: 5:00 p.m.–6:00 p.m.*, Mountain Time, August 9, 2016.

* Please note that the public comment period may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the public comment session at the start time listed.

Place: Residence Inn by Marriott, 635 West Broadway, Idaho Falls, Idaho 83402; Phone: (208) 542–0000; Fax: (208) 542–0021.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 100 people. The public is also welcome to listen to the meeting by joining the teleconference at USA toll-free, dial-in number, 1–866–659–0537 and the pass code is 9933701.

Live Meeting Connection: https://www.livemeeting.com/cc/cdc/join?id=M3QDP7&role=attend&pw=ABRWH; Meeting ID: M3QDP; Entry Code: ABRWH.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016 pursuant to Executive Order 13708, and will expire on September 30, 2017.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters for Discussion: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; Report by the Dose Reconstruction Review Methods Work Group; Dose Reconstruction Report to the Secretary; SEC Petitions Update; Site Profile review for: Pinellas Plant (Clearwater, Florida), and United Nuclear Co. (Hematite, Missouri); SEC petitions for: Area IV of Santa Susana Field Laboratory (1965; Ventura County, California), Argonne National Laboratory West (1951–1979; Scoville, Idaho), Blockson Chemical Company (1960–1991; Joliet, Illinois), Idaho National Laboratory (1949–1970; Scoville, Idaho), Savannah River Site (1973–2007; Aiken, South Carolina), and Westinghouse Electric Co. (1960–2011; Bloomfield, New Jersey); and a Board Work Session.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted to the contact person below well in advance of the meeting. Any written comments received will be provided at the meeting in accordance with the redaction policy provided below.

Policy on Redaction of Board Meeting Transcripts (Public Comment):

(1) If a person making a comment gives his or her personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter.

(2) If an individual in making a statement reveals personal information (*e.g.,* medical or employment information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information.

(3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriate, such information will be redacted, unless the disclosure is made by the third party's authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

(4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure.

The Board will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E–20, Atlanta, Georgia 30333, telephone: (513) 533–6800, toll free: 1–800–CDC–INFO, email: *dcas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–16579 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) GH16–007, Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation.

Times and Dates: 9:00 a.m.–2:00 p.m., EDT, Panel A, August 8, 2016 (Closed); 9:00 a.m.–2:00 p.m., EDT, Panel B, August 9, 2016 (Closed); 9:00 a.m.–2:00 p.m., EDT, Panel C, August 10, 2016 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to FOA GH–007 Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation.

Contact Person for More Information: Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road NE., Mailstop D–69, Atlanta, Georgia 30033, Telephone: (404) 639–4796.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–16582 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requests for Nominations of Candidates and Suggested Meeting Topics for the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Correction: This notice was published in the **Federal Register** on June 7, 2016, 81 FR 36543. The Request for Candidates should read as follows:

Request For Candidates: Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to accomplishing CLIAC's objectives. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable across the fields of microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology), immunology (including histocompatibility), chemistry, hematology, pathology (including histopathology and cytology), or genetic testing (including cytogenetics); representatives from the fields of medical technology, public health, and clinical practice; and consumer representatives. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that Committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for CLIAC membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Candidates should submit the following items to be considered for nomination. The deadline for receipt of materials for the 2017 term is August 1, 2016:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, email address).
- Letter(s) of recommendation from person(s) not employed by the U.S. Department of Health and Human Services.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone (404) 498–2741; or via email at *NAnderson@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–16580 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with sction 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) CK17–1701, Emerging Infections Programs.

Time and Date: 10:00 a.m.–5:00 p.m., EDT, August 30–31, 2016 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Emerging Infections Programs", FOA CK17–1701.

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–16581 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–4224]

Determination That PARAFON FORTE DSC (Chlorzoxazone) Tablets, 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and this determination will allow FDA to continue to approve ANDAs for chlorzoxane tablets, 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–8767.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is the subject of NDA 011529, held by Janssen Research & Development, LLC, and initially approved on August 15, 1958. PARAFON FORTE DSC is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is listed in the "Discontinued Drug Product List" section of the Orange Book.

Flamingo Pharmaceuticals Ltd. submitted a citizen petition dated November 7, 2015 (Docket No. FDA–2015–P–4224), under 21 CFR 10.30, requesting that the Agency determine whether PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16635 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1678]

The Food and Drug Administration Foods and Veterinary Medicine Program's Strategic Plan for Fiscal Years 2016–2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice and request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the "Foods and Veterinary Medicine (FVM) Program's Strategic Plan for Fiscal Years 2016–2025" that covers activities of the Office of Foods and Veterinary Medicine, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine, as well as related efforts by the Office of Global Regulatory Operations and Policy and the Office of Regulatory Affairs. Our strategic plan includes goals and objectives for the next 10 years including our mission to implement the FDA Food Safety Modernization Act (FSMA) enacted in 2011, as well as details on our goals of protecting and enhancing the health of both people and animals. We invite public comment on the plan.

DATES: Submit either electronic or written comments on the strategic plan at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–1678 for "FDA Foods and Veterinary Medicine (FVM) Program's Strategic Plan for Fiscal Years 2016–2025." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mia Mercer, Office of Foods and Veterinary Medicine, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8794.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the FVM Program's Strategic Plan for Fiscal Years 2016–2025 in order to inform the public of our goals for the next 10 years. We are implementing the modernization of FDA's regulatory framework for the FVM Program. We are focused on continuing to drive toward a more proactive, preventive, risk-informed approach to food and feed safety, nutrition, and animal health.

The FVM Program works to ensure the American public has food that is safe and nutritious and that animal drug products are safe and effective. Our priority is to obtain high rates of compliance with standards necessary to protect public health and meet consumer and other stakeholder expectations. Recognizing the unique challenges we face in the area of food safety in the 21st century, Congress enacted FSMA which requires (among other things):

- Comprehensive prevention-oriented food safety standards across the food system;
- mandated domestic inspection frequency, based on risk, to ensure high rates of compliance;
- a national integrated food safety system based on full partnership with States; and
- a new import safety system based on food safety accountability for importers, increased foreign presence, and increased collaboration with foreign governments.

Our FVM Program Strategic Plan takes this statutory framework into account, places high priority on the implementation of FSMA, and focuses on how we plan to modernize our food safety work including:

- An increased focus on obtaining compliance with preventive control standards rather than finding and responding to legal violations after an illness or outbreak has occurred;
- strengthening our technical expertise and capacity to support FDA, industry, and other stakeholders in implementing the new prevention standards;
- furthering federal, State, local, and territorial partnerships, and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide; and
- broadening interaction with foreign partners and increasing oversight of

importers, who will have more responsibility for the safety of imported foods.

Beyond FSMA's implementation, the FVM Program Strategic Plan provides details on our goals of protecting and enhancing the health of people and animals. The active engagement of all stakeholders and partners, both internal and external, is critical to the successful implementation of this plan.

II. Electronic Access

Persons with access to the Internet may obtain the FVM Program Strategic Plan at *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Foods and Veterinary Medicine Program Strategic Plan, FY 2016–2025, available at *http://www.fda.gov/aboutfda/centersoffices/officeoffoods/ucm273269.htm.*
2. Partnership for Food Protection (PFP) Strategic Plan FY 2015 through 2020, available at *http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM423834.pdf.*

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16684 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1659]

Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Bacterial Vaginosis: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of bacterial vaginosis (BV).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1659 for "Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Weinstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6382, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bacterial Vaginosis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of BV. This draft guidance helps define enrollment criteria for BV trials and recommends that such trials be superiority trials. The draft guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of BV, including the characterization of the primary efficacy endpoint.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. In 1998, FDA published a draft guidance entitled ''Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment'' (the 1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16636 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for ''Blockchain and its Emerging Role in Health IT and Health-related Research''; Amendment

AGENCY: Office of the National Coordinator for Health Information Technology, HHS. *Award Approving Official:* Karen DeSalvo, National Coordinator for Health Information Technology.

ACTION: Notice; Amendment.

SUMMARY: This document amends the notice published in **Federal Register**, Friday July 8, 2016, volume 81, pages 44639–44640. This notice updates and extends the submission period to August 8, 2016, limits an investigator or co-investigator to one submission and adds prize details. The ''Use of Blockchain in Health IT and Health-related Research'' Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use in Health IT to address privacy, security and scalability challenges of managing electronic health record and resources. Up to 15 winners will be awarded a cash prize and up to 8 winners may be invited to present their papers at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES:

- Submission period begins: July 7, 2016.
- Submission period ends: August 8, 2016.
- Evaluation begins: August 9, 2016.
- Evaluation ends: August 19, 2016.
- Winners notified: August 22, 2016.
- Winners Announced: August 29, 2016.
- Winner Presentation: September 26–27, 2016.

FOR FURTHER INFORMATION CONTACT: Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690–0213.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

A Blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of Blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data. This nationwide call may be addressed by an individual investigator or an investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may only participate in one submission. Up to 15 of these submissions will be selected as winners. The selection of a White Paper may also result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th, 2016, at NIST Headquarters in Gaithersburg, MD.

Objective

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between Blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of Blockchain technology, examine how the use of Blockchain can advance industry interoperability needs expressed in the ONC's Shared Nationwide Interoperability Roadmap, as well as for Patient Centered Outcomes Research (PCOR), the Precision Medicine

Initiative (PMI), delivery system reform, and other health care delivery needs, as well as provide recommendations for Blockchain's implementation. In addition to a monetary award, winners may also have the opportunity to present their White Papers at an industry-wide "Blockchain & Healthcare Workshop" co-hosted by ONC and NIST.

Submission Requirements

The white paper must:

- Be no longer than ten (10) pages;
- Address whether there is a place in health IT and/or healthcare related research for the technology;
- Describe the value of Blockchain to the health-care system;
- Identify potential gaps in standards created and/or resolved by the use of Blockchain;
- Discuss the effectiveness of Blockchain to function in the "real world." This discussion may include information regarding meeting privacy and security standards, implementation and potential performance issues, and cost implications. Risk analysis and mitigation would be appropriate to include here as well; and
- Discuss how Blockchain links to the stated objectives in the Nationwide Interoperability Roadmap, PCOR, PMI, delivery system reform, and other national health care delivery priorities.

How To Enter

Challenge participants will submit their submission on the challenge Web site [*http://www.cccinnovationcenter.com/challenges/block-chain-challenge*].

Eligibility Rules for Participating in the Challenge

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge.
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.
4. May not be a Federal entity or Federal employee acting within the scope of their employment.
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge Submission.
9. An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.
10. Submissions must not display HHS' or ONC's logos or official seals and must not claim endorsement.
11. Accuracy—A white paper submission may be disqualified if it provides inaccurate or incomplete information.

Registration Process for Participants

To register for this Challenge, participants can access *http://www.challenge.gov* and search for "Blockchain and Its Emerging Role in Healthcare and Health-related Research."

Prize

- 12–15 white papers will be awarded a cash prize in the range of $ 1,500–5,000,
- Up to 8 winners may be given the opportunity to present their paper at a Blockchain & Healthcare Workshop Hosted at NIST,
- Inclusion of the white papers in the Blockchain workshop proceedings.

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

The judging panel will rate each submission based upon:

- Potential of the overall concept to help foster transformative change in the culture of health IT,
- Viability of the proposed recommendations,
- Innovativeness of the approach,
- Potential for achieving the objectives of ONC.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the Challenge. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

(a) Participant is the sole author, creator, and owner of the Submission;

(b) The Submission is not the subject of any actual or threatened litigation or claim;

(c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party.

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal sponsors reserve the right to disqualify any Submission that, in their discretion, deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo, MD., M.P.H., M.Sc.

National Coordinator for Health Information Technology.

[FR Doc. 2016–16607 Filed 7–13–16; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Addictions, Depression, Bipolar Disorder, Schizophrenia.

Date: August 2, 2016.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: HIV and Related Research.

Date: August 3, 2016.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301–451–2796, *bdey@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodegeneration.

Date: August 11, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301–435–1203, *laurent.taupenot@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16589 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Protein Reagent Validation Review.

Date: August 5, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Human Genome Research Institute, 5635 Fishers Lane, Room 3051, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 7, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16593 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular and Social Aspects of Psychiatry through RDOC.

Date: July 28, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Diabetes and Musculoskeletal Epidemiology.

Date: August 1, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: George Vogler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, MSC 7770, Bethesda, MD 20892, (301) 237–2693, *voglergp@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.

Date: August 3, 2016.

Time: 2:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16590 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health.

The meeting will be open to the public, with attendance limited to the number of phone lines. Individuals who plan to attend and need special assistance, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health.

Date: August 12, 2016.

Time: 1 p.m. to 2:30 p.m.

Agenda: To discuss: (1) The Advisory Committee to the Deputy Director for Intramural Research (AC DDIR) Report on the Site Visit Review of the Office of Human Research Subject Research Protection; (2) the recommendations for the Office of Human Subjects Research Protections program; and (3) the AC DDIR Implementation Report.

Place: National Institutes of Health, Teleconference, Participant Passcode: 15443, Conference Line: 888–233–9215, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Margaret McBurney, Program Specialist, Office of the Director for Intramural Research, National Institutes of Health, Building One, Room 160, Bethesda, MD 20892, 301–496–1921, *mmburney@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: July 8, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16595 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel.

Date: July 28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–2849, *dunbarl@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 8, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16594 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Transportation, Tolerance, and Autoimmune.

Date: July 21, 2016.

Time: 3:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301–435–1223, *haydenb@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16591 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special; Emphasis Panel Evans Clinical Trial.

Date: August 3, 2016.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 5635 Fisher Lane, 3rd Floor Conference Room, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 7, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16592 Filed 7–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0093]

Agency Information Collection Activities: Declaration of Owner and Declaration of Consignee When Entry Is Made by an Agent

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Declaration of Owner and Declaration of Consignee When Entry is made by an Agent (Forms 3347 and 3347A). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before August 15, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or via email (*CBP_PRA@cbp.dhs.gov*). Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/*. For additional help: *https://help.cbp.gov/app/home/search/1*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (81 FR 28095) on May 9, 2016, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Declaration of Owner and Declaration of Consignee When Entry is made by an Agent.

OMB Number: 1651–0093.

Form Number: CBP Forms 3347 and 3347A.

Abstract: CBP Form 3347, *Declaration of Owner,* is a declaration from the owner of imported merchandise stating that he/she agrees to pay additional or increased duties, therefore releasing the importer of record from paying such duties. This form must be filed within 90 days from the date of entry. CBP Form 3347 is provided for by 19 CFR 24.11 and 141.20.

When entry is made in a consignee's name by an agent who has knowledge of the facts and who is authorized under a proper power of attorney by that consignee, a declaration from the consignee on CBP Form 3347A, *Declaration of Consignee When Entry is Made by an Agent,* shall be filed with the entry summary. If this declaration is filed, then no bond to produce a declaration of the consignee is required. CBP Form 3347A is provided for by 19 CFR 141.19(b)(2).

CBP Forms 3347 and 3347A are authorized by 19 U.S.C. 1485 and are accessible at *http://www.cbp.gov/xp/cgov/toolbox/forms/*.

Action: CBP proposes to extend the expiration date of this information collection with no change to the estimated burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

CBP Form 3347:

Estimated Number of Respondents: 900.

Estimated Number of Responses per Respondent: 6.

Estimated Total Annual Responses: 5,400.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 540.

CBP Form 3347A:

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent: 6.

Estimated Total Annual Responses: 300.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 30.

Dated: July 11, 2016.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2016–16688 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

Meeting of the Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Notice of Open Federal Advisory Committee Meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will meet on August 29–30, 2016, in Emmitsburg, Maryland. The meeting will be open to the public.

DATES: The meeting will take place on Monday, August 29, 9:30 a.m. to 5:00 p.m. Eastern Daylight Time and on Tuesday, August 30, 8:30 a.m. to 5:00 p.m. Eastern Daylight Time. Please note that the meeting may close early if the Board has completed its business.

ADDRESSES: The meeting will be held at the National Emergency Training Center, 16825 South Seton Avenue, Building H, Room 300, Emmitsburg, Maryland. Members of the public who wish to obtain details on how to gain access to the facility and directions may contact Ruth MacPhail as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business August 15, 2016. Photo identification that meets *REAL ID ACT* standards (*https://www.usfa.fema.gov/training/nfa/admissions/campus_access.html*) is required for access. Members of the public may also participate by teleconference and may contact Ruth MacPhail to obtain the call-in number and access code. For information on services for individuals with disabilities or to request special assistance, contact Ruth MacPhail as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Comments must be submitted in writing no later than August 15, 2016, must be identified by Docket ID FEMA–2008–0010 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FEMA–RULES@fema.dhs.gov.* Include the docket number in the subject line of the message.
- *Mail/Hand Delivery*: Ruth MacPhail, 16825 South Seton Avenue, Emmitsburg, Maryland 21727.

Instructions: All submissions received must include the words "Federal Emergency Management Agency" and the Docket ID for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the National Fire Academy Board of Visitors, go to *http://www.regulations.gov,* click on "Advanced Search," then enter "FEMA–2008–0010" in the "By Docket ID" box, then select "FEMA" under "By Agency," and then click "Search."

FOR FURTHER INFORMATION CONTACT:

Alternate Designated Federal Officer: Kirby E. Kiefer, telephone (301) 447–1117, email *Kirby.Kiefer@fema.dhs.gov.*

Logistical Information: Ruth MacPhail, telephone (301) 447–1333 and email *Ruth.Macphail@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Board of Visitors for the National Fire Academy (Board) will meet on Monday, August 29, and Tuesday, August 30, 2016. The meeting will be open to the public. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (NFA) and advise the Administrator of the Federal Emergency Management Agency (FEMA), through the United States Fire Administrator, on the operation of the NFA and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines NFA programs to determine whether these programs further the basic missions that are approved by the Administrator of FEMA, examines the physical plant of the NFA to determine the adequacy of the NFA's facilities, and examines the funding levels for NFA programs. The Board submits a written annual report through the United States Fire Administrator to the Administrator of FEMA. The report provides detailed comments and recommendations regarding the operation of the NFA.

Agenda

On Monday, August 29, 2016, there will be five sessions, with deliberations and voting at the end of each session as necessary. The Board will also select a Chairperson and Vice Chairperson for Fiscal Year 2017. NFA program activities deliberation will continue on Tuesday, August 30, 2016, if not concluded on Monday.

1. The Board will receive updates on United States Fire Administration data, research, and response support initiatives.
2. The Board will discuss deferred maintenance and capital improvements on the National Emergency Training Center campus and Fiscal Year 2016 Budget Request/Budget Planning.
3. The Board will receive activity reports on the Professional Development Initiative Subcommittee, Whole Community Subcommittee, and National Fire Incident Reporting System Subcommittee.
4. The Board will receive annual ethics training.
5. The Board will deliberate and vote on recommendations on NFA program activities, including:

- The Managing Officer Program, a multiyear curriculum that introduces emerging emergency services leaders to personal and professional skills in change management, risk reduction, and adaptive leadership; a progress report to include pre-program course requirements;
- Curriculum development and revision updates for NFA courses;
- The Executive Fire Officer (EFO) Program assessment results and recommendations;
- The EFO Program application selection results;
- The EFO Program Symposium being held September 10–12, 2016; an annual event for alumni which recognizes outstanding applied research

completed by present EFO Program participants, recognizes recent EFO Program graduates, provides high-quality presentations offered by private and public sector representatives, facilitates networking between EFO Program graduates, promotes further dialog between EFO Program graduates and United States Fire Administrator and National Fire Academy faculty and staff; agenda update;

- Review and update to Coffee Break Training courses;
- Staffing update;
- Discussion on the approval process for state-specific courses;
- Online mediated instruction program update;
- Distance learning program update;
- Fire and Emergency Services Higher Education (FESHE) Recognition Program update, a certification program acknowledging that a collegiate emergency services degree meets the minimum standards of excellence established by FESHE development committees and the NFA;
- The National Professional Development Symposium Report held on June 27–29, 2016 which brought national training and education audiences together for their annual conference and support initiatives.

NFA Program Activities deliberations will continue on Tuesday, August 30, 2016, if not concluded.

On Tuesday, August 30, 2016, the Board will conduct classroom visits and tour the campus facility. The Board will also engage in an annual report writing session. Deliberations or voting may occur as needed during the report writing session.

There will be a 10-minute comment period after each agenda item and each speaker will be given no more than 2 minutes to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact Ruth MacPhail to register as a speaker. Meeting materials will be posted at *https://www.usfa.fema.gov/training/nfa/about/bov.html* by August 15, 2016.

Dated: July 7, 2016.

Kirby E. Kiefer,

Acting Superintendent, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2016–16626 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–45–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: *Effective Date:* July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of West Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 25, 2016.

Jackson and Lincoln Counties for Individual Assistance.

Jackson and Lincoln Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16623 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4269–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4269–DR), dated April 25, 2016, and related determinations.

DATES: Effective June 29, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 25, 2016.

Anderson, Cherokee, Smith, and Wood Counties for Individual Assistance.

Anderson, Cass, Cherokee, Harrison, Jones, Smith, Upshur, Van Zandt, and Wood Counties for Public Assistance.

Fort Bend and Liberty Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16621 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: *Effective:* July 6, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of West Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 25, 2016.

Clay, Fayette, Greenbrier, Jackson, Kanawha, Monroe, Nicholas, Pocahontas, Roane, Summers, and Webster Counties for (Categories A and C–G), under the Public Assistance program (already designated for Individual Assistance and emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program.)

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16614 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4268–DR; Docket ID FEMA–2016–0001]

Mississippi; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Mississippi (FEMA–4268–DR), dated March 25, 2016, and related determinations.

DATES: *Effective Date:* June 24, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jose M. Girot, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Lai Sun Yee as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16611 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0017; OMB No. 1660–0022]

Agency Information Collection Activities: Proposed Collection; Comment Request; Community Rating System (CRS) Program—Application Worksheets and Commentary

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning application for the National Flood Insurance Program's Community Rating System program. This program allows communities to become eligible for discounts on the cost of flood insurance when the communities undertake activities to mitigate anticipated damage due to flooding. The application materials verify and document the community mitigation activities performed and provides the Federal Emergency Management Agency with the information necessary to determine what flood insurance premium discounts are appropriate for participating communities.

DATES: Comments must be submitted on or before September 12, 2016.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2016–0017. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE., Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal Rulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bill Lesser, Program Specialist, Federal Insurance and Mitigation Administration, (202) 646–2807. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Section 541 of the National Flood Insurance Reform Act (NFIRA) of 1994, 42 U.S.C. 4022, requires that a community rating system be established. This ratings system is a voluntary program for communities and it would provide a method by which flood mitigation activities engaged in by these communities could be measured. The effect of this mitigation activity would reduce the exposure of the communities to damages resulting from flooding and in turn reduce the losses incurred as a result of this flooding. To encourage participation, discounts on flood insurance are offered within communities that successfully complete qualified mitigation actions, and the community ratings system provides the ability to measure these actions and to recertify the communities in successive years.

Collection of Information

Title: Community Rating System (CRS) Program—Application Worksheets and Commentary.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0022.

FEMA Forms: FEMA Form 086–0–35, Community Rating System Application Letter of Interest and Quick Check Instructions; FEMA Form 086–0–35A, Community Annual Recertification; and FEMA Form 086–0–35B, Environmental and Historic Preservation Certifications.

Abstract: The Application and Certifications are used by communities that participate in the National Flood Insurance Program's (NFIP) Community Rating System (CRS). The CRS is a voluntary program where flood insurance costs are reduced in communities that implement practices, such as building codes and public awareness activities, which are considered to reduce the risks of flooding and promote the purchase of flood insurance.

Affected Public: State, Local or Tribal government.

Number of Respondents: 1,579.

Number of Responses: 1,579.

Estimated Total Annual Burden Hours: 41,936 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $2,442,795.30. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $5,425,600.00.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: July 6, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–16628 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: *Effective Date:* June 29, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective June 29, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16613 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0015; OMB No. 1660–0080]

Agency Information Collection Activities: Proposed Collection; Comment Request; Application for Surplus Federal Real Property Public Benefit Conveyance and BRAC Program for Emergency Management Use

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the application process for the conveyance of Federal real property for public benefit. The purpose of this application is to implement the processes and procedures for the successful, lawful, and expeditious

conveyance of real property from the Federal Government to public entities such as State, local, city, town, or other like government bodies as it relates to emergency management response purposes, including fire and rescue services. Compliance will ensure that properties will be fully positioned to use at their highest and best potentials as required by General Services Administration and Department of Defense regulations, Federal law, Executive Orders, and the Code of Federal Regulations.

DATES: Comments must be submitted on or before September 12, 2016.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2016–0015. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE., Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Adrian Austin, Building Management Specialist, FEMA, Support Services and Facilities Management Division, 202–212–2099. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Excess Federal real property is defined as property that is no longer mission critical to the needs of the Federal Government. The conveyance and disposal of excess real property is governed by the Federal Property and Administrative Services Act of 1949 (Property Act) as amended, 40 U.S.C. 541, *et seq.,* 40 U.S.C. 553, and applicable regulations (41 CFR parts 102–75.750 through 102.75.815).

Under the sponsorship of Federal Emergency Management Agency (FEMA) the Property Act gives the Administrator of the General Services Administration (GSA) authority to convey Federal real and related surplus property (without monetary consideration) to units of State and local government for emergency management response purposes, including fire rescue services. The scope and philosophy of GSA's real property policies are contained in 41 CFR part 102–71.

Collection of Information

Title: Application for Surplus Federal Real Property Public Benefit Conveyance and BRAC Program for Emergency Management Use.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0080.

FEMA Forms: FEMA Form 119–0–1, Surplus Federal Real Property Application for Public Benefit Conveyance.

Abstract: Use of the Application for Surplus Federal Real Property Public Benefit Conveyance and Base Realignment and Closure (BRAC) Program for Emergency Management Use is necessary to implement the processes and procedures for the successful, lawful, and expeditious conveyance of real property from the Federal Government to public entities such as State, local, county, city, town, or other like government bodies, as it relates to emergency management response purposes, including fire and rescue services. Utilization of this application will ensure that properties will be fully positioned for use at their highest and best potentials as required by GSA and Department of Defense regulations, public law, Executive Orders, and the Code of Federal Regulations.

Affected Public: State, local, or Tribal Government.

Number of Respondents: 20.

Number of Responses: 20.

Estimated Total Annual Burden Hours: 100 burden hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $6,177. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $2,398.97.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: July 6, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–16629 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4272–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4272–DR), dated June 11, 2016, and related determinations.

DATES: *Effective Date:* June 29, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 11, 2016.

Fayette, Harris, Kleberg, Palo Pinto, and Parker Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant;

97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance–Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households–Other Needs; 97.036, Disaster Grants–Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16625 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: Effective June 29, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of West Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 25, 2016.

Pocahontas and Webster Counties for Individual Assistance.

Pocahontas and Webster Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16588 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4269–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Texas (FEMA–4269–DR), dated April 25, 2016, and related determinations.

DATES: Effective June 29, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this declared disaster is now April 17, 2016, through and including April 30, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–16622 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2016–0038]

Privacy Act of 1974; Department of Homeland Security/United States Coast Guard–015 Legal Assistance Case Files System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current DHS system of records titled, "Department of Homeland Security (DHS)/United States Coast Guard (USCG)–015 Legal Assistance Case Files System of Records." This system of records allows DHS/USCG to collect and maintain records regarding legal assistance. As a result of the biennial review of this system, DHS/USCG is updating this system of records notice to clarify the authorities for collection, update the system manager, and update the system location. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before August 15, 2016. This updated system will be effective August 15, 2016.

ADDRESSES: You may submit comments, identified by docket number DHS–2016–0038 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Marilyn Scott-Perez (202–475–3515), Privacy Officer, Commandant (CG–61), United States Coast Guard, Mail Stop 7710, Washington, DC 20593. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) United States Coast Guard (USCG) proposes to update and reissue a current DHS system of records titled, ''DHS/USCG–015 Legal Assistance Case Files System of Records.'' The collection and maintenance of this information will assist DHS/USCG in meeting its statutory obligation in providing personal legal assistance to USCG military personnel. Legal Assistance is a branch of the Judge Advocate General (JAG) CG–094. Legal Assistance is established for all military branches of the Department of Defense and the DHS/USCG by an Act of Congress under 10 U.S.C. 1044. According to sec. 1044, the purpose is to assist qualified individuals and provide legal assistance in connection with their personal civil legal affairs. Eligible personnel are outlined in sec. 1044:

- Military personnel of the armed forces who are on active duty (including reservists on active duty or scheduled for deployment).
- Military personnel and former military personnel entitled to retired or retainer pay or equivalent pay.
- Officers of the commissioned corps of the Public Health Service who are on active duty or entitled to retired or equivalent pay.
- Dependents of military personnel (including dependents of reservists on active duty or scheduled for deployment) and retired military personnel described above.
- Other persons authorized by the Judge Advocate General.

The DHS/USCG–015 Legal Assistance Case Files System of Records are the USCG's record system used for the collection and maintenance of records regarding legal assistance. *As a result of a biennial review of the system,* DHS/USCG is updating this system of records notice to clarify the authorities for collection, update the system manager, and update the system location *to reflect the new mailstop.*

Consistent with DHS's information-sharing mission, information stored in the DHS/USCG–015 Legal Assistance Case Files System of Records may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, information may be shared with appropriate Federal, State, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/USCG–015 Legal Assistance Case Files System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/United States Coast Guard (USCG)–015

SYSTEM NAME:

DHS/USCG–015 Legal Assistance Case Files System of Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at the USCG Headquarters in Washington, DC and field offices. The Case Matter Management Tracking (CMMT) System, also known as ''Law Manager,'' is the information technology (IT) system in which records associated with this function are maintained.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

- Military personnel of the armed forces who are on active duty (including reservists on active duty or scheduled for deployment).
- Military personnel and former military personnel entitled to retired or retainer pay or equivalent pay.
- Officers of the commissioned corps of the Public Health Service who are on active duty or entitled to retired or equivalent pay.
- Dependents of military personnel (including dependents of reservists on active duty or scheduled for deployment) and retired military personnel described above.
- Other persons authorized by the Judge Advocate General.

CATEGORIES OF RECORDS IN THE SYSTEM:

- Categories of records in this system include:
  - ○ Name;
  - ○ Rank;
  - ○ Employee identification number;
  - ○ Date of birth;
  - ○ Duty station;
  - ○ Telephone numbers;
  - ○ Work and home addresses;
  - ○ Case number;
  - ○ Any information within the legal case file concerning the personal matters handled by these offices for clients (*e.g.,* executing wills, power of attorney, separation/divorce, landlord/tenant issues, consumer issues).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 1044; and Commandant Instruction 5801.4E.

PURPOSE(S):

The purpose of this system is to provide legal assistance to eligible clients (active duty armed forces members and their dependents; former members entitled to retired/retainer/equivalent pay and their dependents; commissioned corps of the Public Health Service and the National Oceanic and Atmospheric Administration officers on active duty or entitled to retired or equivalent pay; survivors of members or former members who were eligible for legal assistance when they died; and those persons authorized by the Judge Advocate General) seeking personal legal assistance pursuant to CI 5801.4E. Legal assistance services provided may include; wills and estate planning; military testamentary instruments; advanced medical directives or living wills; Military Advanced Medical Directives (MAMD); Landlord-Tenant and Consumer Affairs disputes; civil suits; tax disputes; adoptions and name changes; domestic relations; powers of attorney; and minor criminal matters. All Coast Guard legal assistance services are described in CI 5801.4E.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS, subject to attorney ethical requirements regarding confidentiality and privilege, as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including offices of the United States Attorney, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;
2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and
3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

DHS/USCG stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

RETRIEVABILITY:

DHS/USCG may retrieve records by name or case number.

SAFEGUARDS:

DHS/USCG safeguards records in this system in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/USCG has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

DHS/USCG destroys or deletes records 3 years after case is closed or when no longer needed by an attorney's state bar, whichever is later. (AUTH: N1–26–06–3, Item 1).

SYSTEM MANAGER AND ADDRESS:

Commandant, (CG–094), United States Coast Guard, Mail Stop 7213, Washington, DC 20593–0001.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Commandant (CG–611), United States Coast Guard, Mail Stop 7710, Washington, DC 20593. If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act (FOIA) Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

Records are obtained directly from the client involved and during any subsequent investigation by the legal officer on behalf of the client.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: June 23, 2016.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–16598 Filed 7–13–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2016–0041]

Privacy Act of 1974; Department of Homeland Security/U.S. Immigration and Customs Enforcement-014 Homeland Security Investigations Forensic Laboratory System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of amendment of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current DHS system of records titled, "Department of Homeland Security/U.S. Immigration and Customs Enforcement-014 Homeland Security Investigations Forensic Laboratory (HSI–FL) System of Records." This system of records allows the DHS/U.S. Immigration and Customs Enforcement (ICE) to collect and maintain records by the HSI–FL. The HSI–FL is a U.S. crime laboratory specializing in scientific authentication; forensic examination; research, analysis, and training related to travel and identity documents; latent and patent finger and palm prints; and audio and video files in support of law enforcement investigations and activities by DHS and other agencies. As a result of a biennial review of this system, DHS/ICE is updating this system of records notice to include minor changes that were made to make the wording consistent with the routine uses of other ICE System of Records Notice (SORN) and in accordance with Appendix I to the Office of Management and Budget (OMB) Circular A–130, Federal Agency Responsibilities for Maintaining Records About Individuals. DHS/ICE made minor changes to: Routine Use G that supports ICE's sharing of information with domestic and international law enforcement agencies when there is a violation, or potential criminal, civil, or regulatory violation of law, rule, regulation, or order; Routine Use H that supports parties involved in court litigation when DHS is a party or has an interest; Routine Use V that supports DHS in making a determination regarding redress for an individual; and the retention and disposal section has been updated to note that the current approved ICE records disposition authority states that all case files, other than war crime cases be destroyed five years after the date of completion of the forensic examination. War crime cases are unscheduled at this time, and thus deemed permanent records.

In addition, a new schedule is currently being reviewed and once approved will provide lengthier retention periods than the current schedule. ICE is proposing that case files related to significant cases such as war crimes, terrorism, and homicide cases should be retained at ICE for 20 years after completion of the investigation and all actions based thereon, and then transferred to the National Archives for permanent retention. Once the schedules are approved the SORN will be updated to reflect the changes. The exemptions for the existing SORN will continue to be unchanged. This updated system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before August 15, 2016. This updated system will be effective August 15, 2016.

ADDRESSES: You may submit comments, identified by docket number DHS–2016–0041 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Lyn Rahilly, Privacy Officer, (202) 732–3300, U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, email: *ICEPrivacy@dhs.gov.* For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) proposes to update and reissue a current DHS system of records titled, "DHS/ICE–014 Homeland Security Investigations Forensic Laboratory System of Records."

The Homeland Security Investigations Forensic Laboratory (HSI–FL) is an accredited crime laboratory located within ICE's Office of Homeland Security Investigations (HSI) that provides a broad range of forensic, intelligence, and investigative support services for ICE, DHS, and many other U.S. and foreign law enforcement agencies. The HSI–FL is the only U.S. crime laboratory specializing in scientific authentication; forensic examination; research, analysis, and training related to travel and identity documents; latent and patent finger and palm prints; and audio and video files in support of law enforcement investigations and activities by DHS and other agencies.

As a result of a biennial review of this system, DHS/ICE is updating this SORN to include minor changes to make the wording consistent with the routine uses of other ICE SORNs and in accordance with Appendix I to OMB Circular A–130, Federal Agency Responsibilities for Maintaining Records About Individuals. DHS/ICE made minor changes to routine use G to support ICE's sharing of information with domestic and international law enforcement agencies when there is a violation, or potential criminal, civil, or regulatory violation of rule, regulation, or order; routine use H to support parties involved in litigation before a court or adjudicative body when DHS is a party or has an interest; and routine use V to support DHS in making a determination regarding redress for an individual. These changes are not intended to alter the purpose of these routine uses but to ensure that ICE's SORNs are using consistent and clear routine use language. Finally, the retention and disposal section has been updated to note the current approved ICE records disposition authority states that all case files, other than war crime cases, be destroyed five years after the date of completion of the forensic examination. War crime cases are unscheduled records at this time, and thus deemed permanent records until a retention period has been approved by the National Archivist.

In addition, a new schedule is currently being reviewed and once approved will provide lengthier retention periods than the current schedule. ICE is proposing that case files related to significant cases such as war crimes, terrorism, and homicide cases should be retained at ICE for 20 years after completion of the investigation and all actions based thereon, and then transferred to the National Archives for permanent retention. Once the schedules are approved the SORN will be updated to reflect the changes.

DHS/ICE issued a Final Rule to exempt this system of records from certain provisions of the Privacy Act on April 2, 2014 (79 FR 18441). These regulations remain in effect. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/ICE–014 Homeland Security Investigations Forensic Laboratory System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Immigration and Customs Enforcement (ICE)–014.

SYSTEM NAME:

DHS/ICE–014 Homeland Security Investigations Forensic Laboratory (HSI–FL).

SECURITY CLASSIFICATION:

Law enforcement sensitive.

SYSTEM LOCATION:

Records are maintained at U.S. Immigration and Customs Enforcement Headquarters in Washington, DC and in field offices, and electronic records are maintained in Laboratory Information Management System (LIMS), Imaged Documents & Exemplars Library (IDEAL), and other IT systems.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

1. Individuals whose information is contained on United States or international travel and identity documents, such as driver's licenses, passports, and other forms of identification, that are maintained in the HSI–FL Library;
2. Individuals whose information is contained on United States or international travel and identity documents, such as driver's licenses, passports, and other forms of identification, that are provided to the HSI–FL for forensic examination during a criminal or administrative law enforcement investigation;
3. Individuals who are the subjects of current or previous law enforcement investigations by other domestic or foreign agencies where the HSI–FL is providing support and assistance;
4. Individuals who are the subjects of current or previous law enforcement investigations into violations of U.S. customs and immigration laws, as well as other laws and regulations within ICE's jurisdiction, including investigations led by other domestic or foreign agencies, where the HSI–FL is providing support and assistance; and
5. Individuals whose image or voice may be captured on video or audio files when the HSI–FL is provided the file to perform technical enhancements of the file.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

1. Biographic, descriptive, historical, and other identifying data, including: Names; photographs; fingerprint identification number; date and place of birth; passport and other travel document information; nationality; aliases; Alien Registration Number (A–Number); Social Security number; other identification numbers, contact or location information (*e.g.,* known or possible addresses, phone numbers); visa information; employment, educational, immigration, and criminal history; height, weight, eye color, hair color, and other unique physical characteristics (*e.g.,* scars and tattoos).
2. Fingerprints or palm prints of individuals whose information is provided to the HSI–FL for forensic examination.
3. Case-related data, including: Case number, record number, and other data describing an event involving alleged violations of criminal or immigration law (such as, location, date, time, event category (event categories describe broad categories of criminal law enforcement, such as immigration worksite enforcement, contraband smuggling, and human trafficking)); types of criminal or immigration law violations alleged; types of property involved; use of violence, weapons, or assault against DHS personnel or third parties; attempted escape; and other related information. ICE case management information, including: Case category; case agent; date initiated; and date completed.
4. Birth, marriage, education, employment, travel, and other information derived from affidavits, certificates, manifests, and other documents presented to or collected by

ICE during immigration and law enforcement proceedings or activities. This data typically pertains to subjects, relatives, and witnesses.

5. Data concerning personnel of other agencies that arrested, or assisted or participated in the arrest or investigation of, or are maintaining custody of an individual whose arrest record is contained in this system of records. This can include: name; title; agency name; address; telephone number; and other information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

8 U.S.C. 1103, 18 U.S.C. 496, 18 U.S.C. 911, 18 U.S.C. 1001, 18 U.S.C. 1028, 18 U.S.C. 1425, 18 U.S.C. 1426, 18 U.S.C. 1427, 18 U.S.C. 1541, 18 U.S.C. 1543, and 18 U.S.C. 1546.

PURPOSE(S):

The purposes of this system are to:

1. Maintain records related to the scientific authentication, examination, research, and analysis of travel and identity documents, fingerprints, and palm prints in accordance with established laboratory policies and procedures, scientific principles, and accreditation standards.

2. Maintain a library of travel and identity documents and associated reference materials for use in forensic examinations, investigations, training, and other activities.

3. Support the forensic examinations on a full range of documents, including but not limited to, passports, visas, driver's licenses, identification cards, border crossing cards, handwritten documents, vital records, and typewritten documents. The analysis may include, but is not limited to, an examination of handwriting, hand printing, typewriting, printing processes, security features, papers, inks, and stamp impressions.

4. Maintain records facilitating the preparation of written laboratory reports and delivery of expert witness testimony in legal proceedings.

5. Support the provision of training in fraudulent document detection, creation of document intelligence alerts and reference guides, and provision of direct assistance to federal, state and local agencies, as well as foreign governments and commercial entities to combat document fraud.

6. Provide assistance within ICE and to domestic and foreign agencies to support the identification and arrest of individuals (both citizens and non-citizens) who commit violations of law.

7. To identify potential criminal activity, immigration violations, and threats to homeland security; to uphold and enforce the law; and to ensure public safety.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ) (including offices of the United States Attorneys) or other federal agency conducting litigation or proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. When a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, rule, regulation, or order, which includes criminal, civil, or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure, a disclosure may be made to the appropriate federal, state, local, tribal, territorial, international, or foreign law enforcement agencies or other appropriate authorities charged with investigating or prosecuting a violation or enforcing or implementing such law, rule, regulation, or order.

H. To courts, magistrates, administrative tribunals, opposing counsel, parties, and witnesses, in the course of immigration, civil, or criminal proceedings (including discovery, presentation of evidence, and settlement negotiations) and when DHS determines that use of such records is relevant and necessary to the litigation before a court or adjudicative body when any of the following is a party to or have an interest in the litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity when the government has agreed to represent the employee; or

4. The United States, when DHS determines that litigation is likely to affect DHS or any of its components.

I. To federal, state, local, tribal, territorial, or foreign government agencies, as well as to other individuals and organizations during the course of an investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of the immigration and nationality laws, when DHS deems that such disclosure is necessary to carry out its functions and statutory mandates or to elicit information required by DHS to carry out its functions and statutory mandates.

J. To federal, state, local, tribal, or territorial government agencies seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency for any purpose authorized by law.

K. To federal, state, local, tribal, or territorial government agencies, or other entities or individuals, or through established liaison channels to selected foreign governments, in order to provide intelligence, counterintelligence, or other information for the purposes of national security, intelligence, counterintelligence, or antiterrorism activities authorized by U.S. law, Executive Order, or other applicable national security directive.

L. To federal, state, local, tribal, territorial, or foreign government agencies or organizations, or international organizations, lawfully engaged in collecting law enforcement intelligence, whether civil or criminal, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence.

M. To international, foreign, intergovernmental, and multinational government agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

N. To federal and foreign government intelligence or counterterrorism agencies or components when DHS becomes aware of an indication of a threat or potential threat to national or international security, or when such disclosure is to support the conduct of national intelligence and security investigations or to assist in anti-terrorism efforts.

O. To federal, state, local, tribal, territorial, or foreign government agencies or entities or multinational government agencies when DHS desires to exchange relevant data for the purpose of developing, testing, or implementing new software or technology whose purpose is related to this system of records.

P. To federal, state, local, territorial, tribal, international, or foreign criminal, civil, or regulatory law enforcement authorities when the information is necessary for collaboration, coordination, and de-confliction of investigative matters, prosecutions, and/or other law enforcement actions to avoid duplicative or disruptive efforts, and to ensure the safety of law enforcement officers who may be working on related law enforcement matters.

Q. To the Department of State in the processing of petitions or applications for benefits under the Immigration and Nationality Act, and all other immigration and nationality laws including treaties and reciprocal agreements; or when the Department of State requires information to consider and/or provide an informed response to a request for information from a foreign, international, or intergovernmental agency, authority, or organization about an alien or an enforcement operation with transnational implications.

R. To the Department of State to provide read-only access of records maintained in the Imaged Documents and Exemplars Library to assist the Department of State with its validation of travel and identity documents.

S. To federal, state, local, tribal, territorial, or foreign government agencies for purposes of completing and providing results of requested forensic examinations to the requesting agency.

T. To the Department of Justice (including offices of the United States Attorneys) or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when necessary to assist in the development of such agency's legal and/or policy position.

U. To the U.S. Senate Committee on the Judiciary or the U.S. House of Representatives Committee on the Judiciary when necessary to inform members of Congress about an alien who is being considered for private immigration relief.

V. To federal, state, local, tribal, territorial, international, or foreign government agencies or entities for the purpose of consulting with that agency or entity: (1) To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program; (2) to verify the identity of an individual seeking redress in connection with the operations of a DHS component or program; or (3) to verify the accuracy of information submitted by an individual who has requested such redress on behalf of another individual.

W. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

ICE stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored in hard copy and electronically on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

ICE may retrieve records by name; identification numbers including case or record number if applicable; other personal identification numbers including Alien Registration Number (A–Number), fingerprint identification number, and other personal identification numbers; and case related data and/or combination of other personal identifiers including, but not limited to, date of birth and nationality.

SAFEGUARDS:

ICE safeguards records in this system in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

The current approved ICE records disposition authority states that all case files not pertaining to war crimes be destroyed five years after the date of completion of the forensic examination. War crime case files are unscheduled at this time, and thus are deemed permanent records.

A new records schedule is currently being reviewed, and once approved, will provide lengthier retention periods than the current schedule. ICE is proposing that case files related to significant cases such as war crimes, terrorism, and homicide cases should be retained at ICE for 20 years after completion of the investigation and all actions based thereon, and then transferred to the National Archives for permanent retention.

Once the schedules are approved, the SORN will be updated to reflect the changes.

SYSTEM MANAGER AND ADDRESS:

U.S. Immigration and Customs Enforcement, Homeland Security Investigations Forensic Laboratory, Unit Chief, 8000 West Park Drive, McLean, VA 22102–3105.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, DHS/ICE will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of, and access to, any record contained in this system of records, or seeking to contest its content, may submit a request in writing to ICE's Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under "Contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, as well as your date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to a lack of specificity or a lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

Records in the system are supplied by several sources. In general, ICE obtains information from federal, state, local, tribal, or foreign governments. More specifically, DHS/ICE–014 records are derived from the following sources: (a) Other federal, state, local, tribal, or foreign governments and government information systems; and (b) evidence, contraband, and other seized material.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act 5 U.S.C. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8); (f); and (g). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). When a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions in accordance with this rule.

Dated: June 23, 2016.

Karen L. Neuman

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–16587 Filed 7–13–16; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[16XD4523WS DWSNN0000.XD0000 DS67010000 DP67012]

Privacy Act of 1974, as Amended; Notice To Amend an Existing System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of amendment to an existing system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior is issuing a public notice of its intent to amend the Department of the Interior Privacy Act system of records, "Privacy Act Files—Interior, DOI–57", to add new routine uses, and update existing routine uses, system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, storage, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, records source categories, and exemption sections.

DATES: Comments must be received by August 15, 2016. This amended system will be effective August 15, 2016.

ADDRESSES: Any person interested in commenting on this amendment may do so by: Submitting comments in writing to Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5545 MIB, Washington, DC 20240; hand-delivering comments to Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5545 MIB, Washington, DC 20240; or emailing comments to *Privacy@ios.doi.gov*.

FOR FURTHER INFORMATION CONTACT: Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5547 MIB, Washington, DC 20240; or by telephone at 202–208–1605.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of the Interior (DOI) maintains the "Privacy Act Files—Interior, DOI–57" system of records. This system enables DOI to efficiently manage Privacy Act Program activities; supports the processing and tracking of notification, record access and amendment requests, and administrative appeals under the Privacy Act; conduct and manage complaints; supports agency participation in litigation arising from such requests, complaints, and appeals; and carry out any other responsibilities under the provisions of the Privacy Act. DOI is publishing this amended notice to reflect updated information in the system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, storage, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, records source categories, and exemption sections.

Additionally, DOI is modifying existing routine uses to reflect updates consistent with standard DOI routine uses, and adding new routine uses to permit sharing of information with: (1) The Office of Management and Budget (OMB) in relation to legislative affairs mandates by OMB Circular A–19; (2) the Department of the Treasury to recover debts owed to the United States; (3) the National Archives and Records Administration (NARA) to conduct records management inspections; (4) NARA, Office of Government Information Services (OGIS) to assist and facilitate the resolution of disputes, to the extent such a dispute involves a combined Freedom of Information Act and Privacy Act request for agency records; (5) Federal, state, territorial, local, tribal, or foreign agencies when there is an indication of a violation of law; (6) Federal, state, territorial, local, tribal, or foreign agencies when relevant for hiring and retention, or issuance of security clearance, license, contract, grant or benefit; (7) appropriate government agencies and organizations to provide information in response to court orders or for discovery purposes related to litigation; (8) an expert, consultant, or contractor that performs services on DOI's behalf to carry out the purposes of the system; (9) another Federal agency to assist that agency in responding to an inquiry by the individual to whom that record pertains; and (10) the news media and the public, with approval by the Public Affairs Officer and Senior Agency Official for Privacy in consultation with Counsel.

The Privacy Act records in this system may also be maintained in other DOI systems of records, "Electronic FOIA Tracking System and FOIA Case Files—Interior, DOI–71" (67 FR 58817) for combined FOIA and Privacy Act requests, and "Freedom of Information Act Appeals Files—Interior, OS–69" (64 FR 16986) for appeals filed on Privacy Act requests or combined FOIA and Privacy Act requests. DOI last published a system notice in the **Federal Register** on March 24, 1999 (64 FR 14258) and published an amended notice on February 13, 2008 (73 FR 8342).

The amendments to the system will be effective as proposed at the end of the comment period (the comment period will end 30 days after the publication of this notice in the **Federal Register**), unless comments are received which would require a contrary determination. DOI will publish a revised notice if changes are made based upon a review of the comments received.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' personal information. The Privacy Act applies to records about individuals that are maintained in a "system of records." A "system of records" is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. As a matter of policy, DOI extends administrative Privacy Act protections to all individuals. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, the routine uses of each system to make agency recordkeeping practices transparent, to notify individuals regarding the uses of their records, and to assist individuals to more easily find such records within the agency. The amended "Privacy Act Files—Interior, DOI–57" system of records notice is published in its entirety below.

In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this system of records to the Office of Management and Budget and to Congress.

III. Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: July 8, 2016.

Teri Barnett,

Departmental Privacy Officer.

SYSTEM NAME:

Privacy Act Files, DOI–57.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is maintained by the Departmental Privacy Office, Office of the Chief Information Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5545 MIB, Washington, DC 20240; other Department of the Interior Office of the Secretary program offices that maintain or process Privacy Act requests, complaints, or appeals; and Department of the Interior bureaus and offices responsible for managing Privacy Act programs and maintaining records about Privacy Act requests, complaints, or appeals. Visit the Department of the Interior Privacy Program Web site for a list of the Department's Privacy contacts: *https://www.doi.gov/privacy/contacts*.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals or their representatives who have submitted Privacy Act requests for notification of the existence of, access to, and petitions for amendment of records; individuals or their representatives who have filed a Privacy Act complaint; individuals or their representatives who have filed Privacy Act appeals; individuals who are the subject of such requests, complaints, or appeals; officials who may be involved in any Privacy Act request, complaint, or appeal; and DOI personnel assigned to handle such requests, complaints, or appeals.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of records created or compiled in response to Privacy Act requests, complaints, and appeals; records relating to accounting of disclosures pursuant to the requirements of the Privacy Act; and records relating to general agency implementation of the Privacy Act. These records may include the original requests, complaints, or appeals; responses to such requests, complaints, or appeals; related memoranda, email, correspondence, notes, accounting of disclosure forms, reports, notices, and other related or supported documentation; and copies of requested records, contested records, and records under appeal. These records may contain the following information: Names, Social Security numbers, dates of birth, home and work addresses, email addresses, telephone numbers, fax numbers, other contact information, driver license numbers, tribal identification numbers, other tribal enrollment data, unique case identifiers, and any other information that is contained in the record that is requested, contested, or is part of the record under appeal.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552a, The Privacy Act of 1974, as amended.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The primary purpose of the Privacy Act Files system of records is to enable DOI to efficiently manage Privacy Act activities. This system supports the processing of notification, record access and amendment requests, complaints, and administrative appeals under the Privacy Act; supports agency participation in litigation arising from such requests, complaints, and appeals; and assists DOI in carrying out any other responsibilities under the provisions of the Privacy Act.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) (a) To any of the following entities or individuals, when the circumstances set forth in paragraph (b) are met:

(i) The U.S. Department of Justice (DOJ);

(ii) A court or an adjudicative or other administrative body;

(iii) A party in litigation before a court or an adjudicative or other administrative body; or

(iv) Any DOI employee acting in his or her individual capacity if DOI or DOJ has agreed to represent that employee or pay for private representation of the employee;

(b) When:

(i) One of the following is a party to the proceeding or has an interest in the proceeding:

(A) DOI or any component of DOI;

(B) Any other Federal agency appearing before the Office of Hearings and Appeals;

(C) Any DOI employee acting in his or her official capacity;

(D) Any DOI employee acting in his or her individual capacity if DOI or DOJ has agreed to represent that employee or pay for private representation of the employee;

(E) The United States, when DOJ determines that DOI is likely to be affected by the proceeding; and

(ii) DOI deems the disclosure to be:

(A) Relevant and necessary to the proceeding; and

(B) Compatible with the purpose for which the records were compiled.

(2) To a congressional office in response to a written inquiry that an individual covered by the system, or the heir of such individual if the covered individual is deceased, has made to the office.

(3) To any criminal, civil, or regulatory law enforcement authority (whether Federal, state, territorial, local, tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

(4) To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

(5) To Federal, state, territorial, local, tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

(6) To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

(7) To state, territorial and local governments and tribal organizations to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

(8) To an expert, consultant, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

(9) To appropriate agencies, entities, and persons when:

(a) It is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; and

(b) DOI has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interest, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DOI or another agency or entity) that rely upon the compromised information; and

(c) The disclosure is made to such agencies, entities and persons who are reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(10) To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A–19.

(11) To the Department of the Treasury to recover debts owed to the United States.

(12) To the news media and the public, with the approval of the Public Affairs Officer in consultation with Counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

(13) To a debt collection agency for the purpose of collecting outstanding debts owed to the Department for fees associated with processing Privacy Act requests.

(14) To other Federal, state, and local agencies having a subject matter interest in a request or an appeal or a decision thereon.

(15) To another Federal agency to assist that agency in responding to an inquiry by the individual to whom that record pertains.

(16) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(b), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS's offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies, and to the extent such a dispute involves a combined FOIA and Privacy Act request for agency records.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Pursuant to 5 U.S.C. 552a(b)(12), disclosures may be made to a consumer reporting agency as defined in the Fair

Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1996 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are contained in file folders stored within filing cabinets in secured rooms. Electronic records are contained in computers, compact discs, computer tapes, removable drives, email, diskettes, and electronic databases.

RETRIEVABILITY:

Information can be retrieved by specific data elements including: The name of the requester and case tracking number.

SAFEGUARDS:

The records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security and privacy rules and policies. During normal hours of operation, paper records are maintained in locked filed cabinets under the control of authorized personnel. Computerized records systems follow the National Institute of Standards and Technology privacy and security standards as developed to comply with the Privacy Act of 1974 (5 U.S.C. 552a); Public Law 93–579), the Paperwork Reduction Act of 1995 (Pub. L. 104–13); the Federal Information Security Modernization Act of 2014 (Pub. L. 113–283, 44 U.S.C. 3554); and the Federal Information Processing Standards 199, Standards for Security Categorization of Federal Information and Information Systems. Computer servers on which electronic records are stored are located in secured DOI facilities with physical, technical and administrative levels of security to prevent unauthorized access to the DOI network and information assets. Security controls include encryption, firewalls, audit logs, and network system security monitoring.

Electronic data is protected through user identification, passwords, database permissions and software controls. Access to records in the system is limited to authorized personnel who have a need to access the records in the performance of their official duties, and each user's access is restricted to only the functions and data necessary to perform that person's job responsibilities. System administrators and authorized users are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training and sign the DOI Rules of Behavior.

RETENTION AND DISPOSAL:

Records in this system are maintained under Departmental Records Schedule (DRS) 1—Administrative Records, which has been approved by NARA (DAA–0048–2013–0001). DRS–1 is a Department-wide records schedule that covers Privacy Act request files, correspondence, reports, and program administration records related to implementation of the Privacy Act. The disposition for these records is temporary. Privacy Act request files, correspondence, and other short-term administration records are destroyed three years after cut-off, which is generally after the date of reply or the end of the fiscal year in which files are created. Long-term records that require additional retention, such as denials, amendment case files, and files regarding erroneous release of personal information not associated with specific individuals, are destroyed seven years after cut-off, which is generally when the record is closed.

Records not covered by DRS–1 are maintained under General Records Schedule (GRS) 4.2, Information Access and Protection Records. GRS 4.2 item 050, Privacy Act Accounting of Disclosure files, are disposed of in accordance with the subject individual records, or five years after the disclosure, whichever is later. GRS 4.2 item 060, erroneous release files associated with specific records, generally follow the original records disposition or are destroyed six years after the erroneous release, whichever is later.

Paper records are disposed of by shredding or pulping, and records contained on electronic media are degaussed or erased in accordance with 384 Departmental Manual 1 and NARA guidelines.

SYSTEM MANAGER AND ADDRESS:

(1) Departmental Privacy Officer, Office of the Chief Information Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5545 MIB, Washington, DC 20240.

(2) DOI Bureau and Office Privacy Officers. To obtain a current list of the Privacy Officers and their addresses, visit the DOI Privacy Program Web site at *https://www.doi.gov/privacy/contacts.*

(3) Privacy Act System Managers. (Consult DOI system of records notices for addresses of Privacy Act System Managers: *https://www.doi.gov/privacy/sorn.*)

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records on himself or herself should send a signed, written inquiry to the applicable System Manager as identified above. The request envelope and letter should both be clearly marked "PRIVACY ACT INQUIRY." A request for notification must meet the requirements of 43 CFR 2.235.

RECORDS ACCESS PROCEDURES:

An individual requesting records on himself or herself should send a signed, written inquiry to the applicable System Manager as identified above. The request should describe the records sought as specifically as possible. The request envelope and letter should both be clearly marked "PRIVACY ACT REQUEST FOR ACCESS." A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORDS PROCEDURES:

An individual requesting corrections or the removal of material from his or her records should send a signed, written request to the applicable System Manager as identified above. A request for corrections or removal must meet the requirements of 43 CFR 2.246.

RECORD SOURCE CATEGORIES:

Information collected in this system is submitted by individuals or their representatives filing Privacy Act requests, complaints, or appeals; system managers or other officials involved in these requests, complaints, or appeals; and DOI personnel processing these requests, complaints, or appeals. Records are also obtained from DOI systems of records from which Privacy Act requests are made. Information or records in this system may be obtained from combined FOIA and Privacy Act requests processed and maintained under the "Electronic FOIA Tracking System and FOIA Case Files—Interior, DOI–71" system of records; and from appeals records maintained under the "Freedom of Information Act Appeals Files—Interior, OS–69" system of records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemptions are claimed for this system. However, to the extent that copies of exempt records from other systems of records are entered into this system, DOI claims the same exemptions for those records that are claimed for the original primary systems of records from which they originated.

[FR Doc. 2016–16627 Filed 7–13–16; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21370]; [PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Federal Bureau of Investigation, Indianapolis Field Office, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Federal Bureau of Investigation (FBI) has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Federal Bureau of Investigation. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Federal Bureau of Investigation at the address in this notice by August 15, 2016.

ADDRESSES: Federal Bureau of Investigation, Indianapolis Field Office, Attn: Special Agent Timothy Carpenter, 8825 Nelson B. Klein Parkway, Indianapolis, IN 46250, telephone (317) 845–2413, email *artifacts@ic.fbi.gov*.

SUPPLEMENTARY INFORMATION: Notice is hereby given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Federal Bureau of Investigation (FBI), Indianapolis Field Office. The human remains and associated funerary objects were removed from Lyman County, SD.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the FBI in consultation with representatives of the Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; the Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota; the Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota, hereafter referred to as "The Tribes".

History and Description of the Remains

In July 1961, human remains representing, at minimum, 9 individuals were removed from at or near site 39LM0047 in Lyman County, SD. The human remains were later transported to Indiana, where they remained as part of a private collection of Native American antiquities and cultural heritage. In April 2014, the human remains were seized by the FBI as part of a criminal investigation.

The human remains represent one adolescent male, one adolescent female, two adolescents of unknown sex, two adults of unknown sex, one female aged approximately 75 years at time of death, and two individuals of unknown age or sex. No known individuals were identified. The 21 associated funerary objects are 2 lots of glass trade beads; 2 pipestone/Catalinite pipes; 1 unidentified metal stake or nail; 1 metal knife with wooden handle; 1 black metal pendant; 1 drilled metal pendant; 2 stone projectile points; 1 ceramic ink well; 1 ground stone (possibly a pestle); and 1 hammer stone.

Site 39LM0047 is located at the convergence of the White River and the Missouri River. The area is currently under the control, and managed by, the South Dakota Game, Fish and Parks (SDGFD), pursuant to a 1999 transfer of property by the United States Army Corps of Engineers (USACE). However, at the time of the excavation of these human remains and associated funerary objects, the land at the site in question was under the control, and managed by, the USACE.

Site analysis, along with oral history from local tribal nations, indicates that this area was historically inhabited by several populations. Archeologists believe that Siouan-speaking people ancestral to the Mandan lived in this locale from at least A.D. 800 until they were displaced by Caddoan-speaking ancestors of the Arikara. Ancestral Arikara remained in the area until the mid-to-late 1800s, when they moved upstream to join the Mandan and Hidatsa as part of the Three Affiliated tribes. Siouan-speaking peoples ancestral to the Dakota, Lakota, and Nakota hunted across the Plains and often traded with the ancestral Arikara, Mandan, and Hidatsa well ahead of European contact and into the historic period. This particular locale was dominated by the Dakota and Lakota by the early 1700s.

Based upon historical record, site analysis, evidence obtained through criminal investigation, osteological analysis, and tribal consultation, the FBI believes that there is a relationship of shared group identity that can be reasonably traced between the Native American human remains, and associated funerary objects, and The Tribes.

Determinations Made by the Federal Bureau of Investigation

Officials of the FBI have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 9 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 21 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of a death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice who wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Federal Bureau of Investigation, Indianapolis Field Office, Attn: Special Agent Timothy Carpenter, 8825 Nelson B. Klein Parkway, Indianapolis, IN 46250, telephone (317) 845–2413, email *artifacts@ic.fbi.gov*, by August 15, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The FBI is responsible for notifying The Tribes that this notice has been published.

Dated: July 7, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–16608 Filed 7–13–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21395; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Alabama Museums, Tuscaloosa, AL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Alabama Museums has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and a present-day Indian tribe. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the University of Alabama Museums. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian tribe stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the University of Alabama Museums at the address in this notice by August 15, 2016.

ADDRESSES: Dr. Bill Bomar, Executive Director, University of Alabama Museums, Box 870340, Tuscaloosa, AL 35487, telephone (205) 348–7552.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the University of Alabama Museums, Tuscaloosa, AL. The human remains and associated funerary objects were removed from an undocumented bluff shelter along the Warrior River in Blount County, AL.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the University of Alabama Museums professional staff in consultation with the Choctaw Nation of Oklahoma. On October 21, 2015, an updated inventory was sent to the Absentee-Shawnee Tribe of Indians of Oklahoma, Alabama-Coushatta Tribe of Texas (previously listed as the Alabama Coushatta Tribes of Texas), Alabama-Quassarte Tribal Town, Cherokee Nation, Coushatta Tribe of Louisiana, Eastern Band of the Cherokee Indians, Eastern Shawnee Tribe of Oklahoma, Kialegee Tribal Town, Mississippi Band of Choctaw Indians, Poarch Band of Creeks (previously listed as the Parch Band of Creek Indians of Alabama), Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)), The Chickasaw Nation, The Choctaw Nation of Oklahoma, The Muscogee (Creek) Nation, The Seminole Nation of Oklahoma, Thlopthlocco Tribal Town, Tunica-Biloxi Indian Tribe, and the United Keetoowah Band of the Cherokee Indians in Oklahoma.

History and Description of the Remains

In late 1963, the University of Alabama Museums was contacted regarding human remains representing a minimum of one individual removed from an unknown site in Blount County, AL, near the US 31 bridge over the Warrior River. There is a letter on file referencing these human remains, dated November 19, 1963. At an unknown date after November 1963, these human remains were donated to The University of Alabama Museums by Mr. Ferril Goodwin, Sumiton, AL. No known individuals were identified. These human remains were included in a NAGPRA inventory (Human Remains ID 3925 in Unaffiliated Remains: Part 5, Warrior River Survey Project Collection). At a later date, associated artifacts were identified in the collection, along with a note linking the artifacts to the human remains. The two associated funerary objects are fragments of 1 large, rectangular woven cane basket and 4 fragments of an unidentified wooden object. Based on the style and technology of the basket, the University of Alabama Museums believe the likely cultural affiliation of the human remains is Choctaw.

Determinations Made by the University of Alabama Museums

Officials of the University of Alabama Museums have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the two objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects to The Choctaw Nation of Oklahoma.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Bill Bomar, Executive Director, University of Alabama Museums, Box 870340, Tuscaloosa, AL 35487, telephone (205) 348–7552, by August 15, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Choctaw Nation of Oklahoma may proceed.

The University of Alabama Museums is responsible for notifying to the Absentee-Shawnee Tribe of Indians of Oklahoma, Alabama-Coushatta Tribe of Texas (previously listed as the Alabama Coushatta Tribes of Texas), Alabama-Quassarte Tribal Town, Cherokee Nation, Coushatta Tribe of Louisiana, Eastern Band of the Cherokee Indians, Eastern Shawnee Tribe of Oklahoma, Kialegee Tribal Town, Mississippi Band of Choctaw Indians, Poarch Band of Creeks (previously listed as the Parch Band of Creek Indians of Alabama), Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)), The Chickasaw Nation, The Choctaw Nation of Oklahoma, The Muscogee (Creek) Nation, The Seminole Nation of Oklahoma, Thlopthlocco Tribal Town, Tunica-Biloxi Indian Tribe, and the United Keetoowah Band of the Cherokee Indians in Oklahoma that this notice has been published.

Dated: June 27, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–16609 Filed 7–13–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR85854000; XXXR4524KS; RR.4888TR11.0040001]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation intends to seek approval of the following proposed information collection: Collection and Compilation of Water Pipeline Field Performance Data. Before submitting the information collection request to the Office of Management and Budget for approval, the Bureau of Reclamation is soliciting public comments on this information collection.

DATES: Submit written comments on the information collection on or before September 12, 2016.

ADDRESSES: Send all written comments to Dr. Lee Sears, Materials and Corrosion Laboratory, 86–68540, Bureau of Reclamation, P.O. Box 25007, Denver, Colorado 80225; or via email to *lsears@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: To request more information on this information collection, please contact Dr. Lee Sears at 303–445–2392.

SUPPLEMENTARY INFORMATION:

I. Abstract and Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Bureau of Reclamation (Reclamation) has obtained the services of an outside entity to collect data on water pipelines. The information requested is required to comply with a request from Congress for Reclamation to assemble data on pipeline reliability for specific types of pipes.

A **Federal Register** notice announcing the collection of this information was initiated on February 26, 2014 (79 FR 10842), offering the public a 60-day public comment period. A summary of comments received during the 60-day comment period, disposition of comments, and revised information collection were published in the **Federal Register** on October 1, 2014 (79 FR 59291), and the public comment period was reopened for another 30 days. In response to the public's request for additional time to comment, a third notice was published in the **Federal Register** on October 30, 2014 (79 FR 64622), extending the comment period another 30 days. In total, the public was provided 120 days to comment on the ICR. Also at the public's request, all draft supporting documents were made available to the public for consideration.

The contract with Reclamation's previous partners, Battelle and Water Research Foundation, was terminated in July 2015. Reclamation has now obtained the services of Virginia Tech to develop a new survey to collect and assemble data on pipeline reliability.

II. Data

Title: Collection and Compilation of Water Pipeline Field Performance Data.

OMB Control Number: 1006–XXXX.

Description of respondents: Water utility and Federal facility pipe data managers.

Frequency: One-time collection.

Estimated completion time: 10 minutes (making participation decision); 30 minutes (introductory webinar); and 110 minutes (uploading data). The total estimated time is 150 minutes for each respondent.

Estimated Total Number of Respondents: 600 (making participation decision).

Estimated Number of Responses per Respondent: 1.

Estimated Total of Annual Responses: 310.

Estimated Total Annual Burden Hours on Respondents: 100 hours (making participation decision); 155 hours (introductory webinar); and 568 hours (uploading data), for a combined total of 823 hours.

III. Request for Comments

We invite your comments on:

(a) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical use;

(b) the accuracy of our burden estimate for the proposed collection of information;

(c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

We will summarize all comments received regarding this notice. We will publish that summary in the **Federal Register** when the information collection request is submitted to OMB for review and approval.

IV. Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 30, 2016.

Richard W. LaFond,

Chief, Civil Engineering Services Division, Bureau of Reclamation.

[FR Doc. 2016–16644 Filed 7–13–16; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–562 and 731–TA–1329 (Preliminary)]

Ammonium Sulfate From China; Determinations

On the basis of the record developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of ammonium sulfate from China, provided for in subheading 3102.21.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be subsidized by the government of China and sold in the United States at less than fair value ("LTFV").

Commencement of Final Phase Investigations

Pursuant to § 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the Department of Commerce ("Commerce") of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On May 25, 2016, Pasadena Commodities International Nitrogen, LLC, Pasadena, Texas, filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized and LTFV imports of certain ammonium sulfate from China. Accordingly, effective May 25, 2016, the Commission, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701 TA 562 and antidumping duty investigation No. 731–TA–1329 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 1, 2016 (81 FR 35055). The conference was held in Washington, DC, on June 15, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on July 11, 2016. The views of the Commission are contained in USITC Publication 4624 (July 2016), entitled *Ammonium Sulfate from China: Investigation Nos. 701 TA–562 and 731–TA–1329 (Preliminary).*

By order of the Commission.

Issued: July 11, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–16669 Filed 7–13–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0040]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for an Amended Federal Firearms License (ATF F 5300.38)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 12, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tracey Robertson, Acting Chief, Federal Firearms Licensing Center, 244 Needy Road, Martinsburg, WV 25405 at email or telephone: *Tracey.Robertson@atf.gov* or (304) 616–4647. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83–I):* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Application for an Amended Federal Firearms License.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF F 5300.38.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): None.

Abstract: The Gun Control Act requires that each person applying for a Federal Firearms License (FFL) change of address must certify compliance with the provisions of the law for the new address. The ATF F 5300.38, Application for an Amended Federal Firearms License is the application method used by existing Federal Firearms licensees to change the business address of the license and certify compliance. Licensees are required to notify ATF of the intent to move any business premises no later than 30 days prior to the intended move.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 18,000 respondents will take 30 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the*

collection: The estimated annual public burden associated with this collection is 9,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: July 11, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–16656 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[Docket No. FBI]

FBI Criminal Justice Information Services Division; User Fee Schedule

AGENCY: Federal Bureau of Investigation (FBI), Justice.

ACTION: Notice.

SUMMARY: This notice establishes revised rates for the user fee schedule for authorized users requesting fingerprint-based and name-based Criminal History Record Information (CHRI) checks for noncriminal justice purposes.

DATES: This revised fee schedule is effective October 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Robin A. Stark-Nutter, Section Chief, Resources Management Section, Criminal Justice Information Services (CJIS) Division, FBI, 1000 Custer Hollow Road, Module E–3, Clarksburg, WV 26306. Telephone number (304) 625–2910.

SUPPLEMENTARY INFORMATION: Pursuant to the authority in Public Law 101–515, as amended, the FBI has established user fees for authorized agencies requesting noncriminal justice fingerprint-based and name-based CHRI checks. In accordance with the requirements of 28 CFR 20.31(e), the FBI periodically reviews the process of providing fingerprint-based and name-based CHRI checks to determine the proper fee amounts that should be collected, and the FBI publishes any resulting fee adjustments in the **Federal Register**.

A fee study was conducted in keeping with 28 CFR 20.31(e)(2) and employed the same methodology as detailed in the **Federal Register** establishing the process for setting fees (75 FR 18751, April 13, 2010). The fee study results recommended reduced fingerprint-based and name-based CHRI checks from the current user fees published October 27, 2014 (79 FR 63943), which have been in effect since February 1, 2015. The fee study also recommended the elimination of the interim fees set for "Rap Back." Rap Back is an optional service offered by the FBI that provides authorized users with the capability to enroll an individual in a program in order to receive notification of subsequent triggering information, such as a new criminal arrest or the disposition of an old arrest, involving that individual during the term of enrollment. The fee study recommended that the cost of the optional Rap Back program be included as part of the revised fingerprint-based CHRI fees.

The FBI independently reviewed the recommendations, compared them to current fee calculations and plans for future service, and determined that the revised fees were both objectively reasonable and consistent with the underlying legal authorities. Pursuant to the recommendations of the study, the fees for fingerprint-based CHRI checks will be decreased and the fee for name-based CHRI checks will be decreased for federal agencies specifically authorized by statute, *e.g.*, pursuant to the Security Clearance Information Act, 5 U.S.C. 9101. The interim Rap Back fee will be eliminated.

The following tables detail the new fee amounts for authorized users requesting fingerprint-based and name-based CHRI checks for noncriminal justice purposes, including the difference from the fee schedule currently in effect.

FINGERPRINT-BASED CHRI CHECKS

Service	Fee currently in effect	Fee currently in effect for CBSPs[1]	Change in fee amount	Revised fee	Revised fee for CBSPs
Fingerprint-based Submission	$14.75	$12.75	($2.75)	$12.00	$10.00
Fingerprint-based Volunteer Submission (*see* 75 FR 18752)	13.50	11.50	(2.75)	10.75	8.75

[1] Centralized Billing Service Providers, see 75 FR 18753.

NAME-BASED CHRI CHECKS

Service	Fee currently in effect	Change in fee amount	Revised fee
Name-based Submission	$2.25	($0.25)	$2.00

Dated: July 8, 2016.

James B. Comey,

Director, Federal Bureau of Investigation.

[FR Doc. 2016–16610 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Justice for United States Victims of State Sponsored Terrorism Act

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: The Justice for United States Victims of State Sponsored Terrorism Act ("USVSST Act" or "Act"), part of the Consolidated Appropriations Act of 2016, establishes a fund, overseen by a Special Master, to provide compensation to certain eligible individuals who were injured in acts of state sponsored terrorism. The fund will award payment to victims of acts of international terrorism based on final judgments obtained in U.S. district courts against a state sponsor of terrorism, as well as to hostages held at the United States Embassy in Tehran,

Iran, during the period beginning November 4, 1979, and ending January 20, 1981, and their spouses and children. This Notice describes the eligibility requirements and provides procedures for the submission and consideration of applications to the fund.

DATES: This Notice is effective July 14, 2016.

FOR FURTHER INFORMATION CONTACT: The Special Master, United States Victims of State Sponsored Terrorism Fund, or the Chief, Program Management and Training Unit, Asset Forfeiture and Money Laundering Section, Criminal Division, Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20530–0001, telephone (202) 353–2046.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Division O, section 404 of the Consolidated Appropriations Act of 2016, Public Law 114–113 ("Justice for United States Victims of State Sponsored Terrorism Act"), codified at 42 U.S.C. 10609, the U.S. Victims of State Sponsored Terrorism Fund ("Fund") was established to provide compensation to individuals who were injured as a result of an international act of terrorism by a state sponsor of terrorism. Under 42 U.S.C. 10609(c), an eligible claimant is (1) a U.S. person, as defined in 42 U.S.C. 10609(j)(8), with a final judgment issued by a U.S. district court under state or federal law against a state sponsor of terrorism and arising from an act of international terrorism, for which the foreign state was found not immune under provisions of the Foreign Sovereign Immunities Act, codified at 28 U.S.C. 1605A or 1605(a)(7) (as such section was in effect on January 27, 2008); (2) a U.S. person, as defined in 42 U.S.C. 10609(j)(8), who was taken and held hostage from the United States Embassy in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, or the spouse and child of that U.S. person at that time, and who is also identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia; or (3) the personal representative of a deceased individual in either of those two categories.

Following his appointment by the Attorney General, Kenneth Feinberg entered on duty as the Special Master to administer the Fund on May 17, 2016. The Special Master will consider applications, make determinations of eligibility, and calculate payment amounts in accordance with the Act. The determinations of the Special Master are final and not reviewable by any court.

Claims based on eligibility for those persons with final judgments dated before July 14, 2016 and those who qualify as an Iran hostage, or spouse or child thereof, must be filed on or before October 12, 2016. Claims based on eligibility for those persons who obtain final judgments on or after July 14, 2016 must be filed within 90 days of the date of obtaining those judgments. Payments from the Fund are made by the U.S. government, which in turn obtains the right of subrogation to each award. Pursuant to 42 U.S.C. 10609(d)(2), the Special Master shall authorize all initial payments to satisfy eligible claims not later than one year after the date of the enactment of the Act.

The Special Master is issuing this Notice pursuant to section 10609(b)(2) of the Act, which provides that the Special Master shall publish a notice specifying the procedures necessary for United States persons to apply and establish eligibility for payment, including procedures by which eligible United States persons may apply by and through their attorney. The notice is procedural in nature, specifying how to apply for compensation and merely restating the eligibility requirements in the Act; it does not create new rights or impose obligations independent of the statute. It also notes certain instances where the Special Master has discretion about implementing the procedures.

This Notice does not provide a complete overview of the Fund. More detailed information regarding the Fund, including answers to frequently asked questions ("FAQs"), is available on the U.S. Victims of State Sponsored Terrorism Fund Web site at *www.usvsst.com.* Furthermore, the Special Master cannot anticipate all of the issues that may arise over the lifetime of the Fund and that he may have to resolve in the course of making determinations on individual claims.

Administrative Certifications

Pursuant to section 404(b)(2)(A) of Division O of Public Law 114–113, the Consolidated Appropriations Act of 2016, this Notice is exempt from the notice and comment requirements of 5 U.S.C. 553, and it is effective upon issuance. Although not required, in an effort to provide transparency, the Special Master posted a discussion draft of procedures and FAQs on the *www.usvsst.com* Web site and invited input from the public from June 17, 2016 through June 29, 2016. Further, on June 24, 2016 and June 29, 2016, the Special Master hosted public conference calls to provide potential claimants, their lawyers, and any other parties with the opportunity to ask questions concerning the Act, application procedures, and FAQs. The Special Master also met with victims' advocates. The Special Master considered all the input in drafting the Notice and will accept public input made following publication if any adjustments or clarifications are necessary and appropriate.

Because the Special Master is not required to publish a general notice of proposed rulemaking, this Notice is not subject to the provisions of the Regulatory Flexibility Act, as provided in 5 U.S.C. 601(2) and 604(a). This Notice meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, "Civil Justice Reform." This Notice has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review" section 1(b), The Principles of Regulation, and in accordance with Executive Order 13563, "Improving Regulation and Regulatory Review" section 1, General Principles of Regulation. The Special Master has determined that this Notice is not a "significant regulatory action" under Executive Order 12866, Regulatory Planning and Review, section 3(f), and accordingly this Notice has not been reviewed by the Office of Management and Budget.

This Notice, which sets forth procedures for submission and processing of claims under the Fund, pertains to matters of agency practice and procedure and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a "rule" as that term is used by the Congressional Review Act, 5 U.S.C. 804(3)(C), and the reporting requirement of 5 U.S.C. 801 does not apply.

Paperwork Reduction Act of 1995

This Notice implements 42 U.S.C. 10609, which established the Fund. In order to evaluate claims and provide payment on eligible claims, the Special Master must collect certain information from (1) a U.S. person, as defined in 42 U.S.C. 10609(j)(8), with a final judgment issued by a U.S. district court under state or federal law against a state sponsor of terrorism and arising from an act of international terrorism, for which the foreign state was found not immune under provisions of the Foreign Sovereign Immunities Act, codified at 28 U.S.C. 1605A or 1605(a)(7) (as such section was in effect on January 27, 2008); (2) a U.S. person, as defined in 42 U.S.C. 10609(j)(8), who was taken and held hostage from the United States Embassy in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, or the spouse and child of that U.S. person at that time, and who is also identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia; or (3) the personal representative of a deceased individual in either of those two categories.

Accordingly, the Department of Justice, Criminal Division, has submitted an information collection request to the Office of Management and Budget for review and clearance in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995.

Privacy Act of 1974

Elsewhere in the **Federal Register**, the Department of Justice, Criminal Division, has published a notice of a new Privacy Act system of records entitled "U.S. Victims of State Sponsored Terrorism Fund (USVSSTF) File System", JUSTICE/CRM–029. By law, a notice addressing certain administrative matters for the Fund was to be issued within the 60-day period after the Special Master's appointment as established by Congress. In compliance with that time period, the Privacy Act system of records notice published concurrently in the **Federal Register** will become effective upon publication, subject to a 30-day comment period for the routine uses claimed in the notice. In the interim, disclosures necessary to process applications are being made, and will be made, only with the prior written consent of applicants or as otherwise authorized under 5 U.S.C. 552a(b).

Procedures for Applying for Payment From the United States Victims of State Sponsored Terrorism Fund

Part I. Applicant Information

Application forms will be available online at *www.usvsst.com;* by sending a request in writing to the U.S. Victims of State Sponsored Terrorism Fund, c/o GCG, P.O. Box 10229, Dublin, OH 43017–5899; by email to *info@usvsst.com;* by calling (855) 720–6966; or by calling collect at +1 (614) 553–1013 if outside the United States.

Each applicant must submit his or her own application and provide the following information:

1. The applicant's name, address, telephone number, electronic mail address, and, if available, Social Security Number or Tax Identification Number and facsimile number.

2. If the applicant is represented by counsel, name(s), address(es), telephone number(s), electronic mail address(es), facsimile number(s) of counsel, and documentation of counsel's authority to represent the applicant.

3. If the applicant is the estate of a deceased individual, the name, address, telephone number, electronic mail address, and facsimile number, if available, for the Personal Representative of the decedent.

The Special Master will not publish the names of the individuals who have filed for compensation under the Fund and the names of the decedents for whom compensation is sought under the Fund.

Part II. Submission of the Application

Applications may be submitted online at *www.usvsst.com;* by mail to the U.S. Victims of State Sponsored Terrorism Fund, c/o GCG, P.O. Box 10299, Dublin, OH 43017–5899; by overnight mail to the U.S. Victims of State Sponsored Terrorism Fund, c/o GCG, 5151 Blazer Parkway, Suite A, Dublin, OH 43017; by email at *info@usvsst.com;* or toll-free by facsimile for domestic callers at (855) 409–7130 and for international callers at (614) 553–1426. If an applicant is represented by counsel, his or her application may be submitted through counsel, and counsel must submit a separate application on behalf of each represented individual. Only one application may be submitted for each claim.

Part III. General Eligibility

The applicant has the burden of establishing eligibility for payment under the Act. The statutory definitions at 42 U.S.C. 10609(j) are fully incorporated herein.

The Act requires that in order to demonstrate eligibility for payment, an applicant must:

1. Be a U.S. person who holds a final judgment issued by a United States district court under State or Federal law against a state sponsor of terrorism, awarding the applicant compensatory damages on a claim(s) brought by the applicant arising from acts of international terrorism for which the foreign state, or instrumentality of the foreign state, was found not immune from the jurisdiction of the courts of the United States under section 1605A or section 1605(a)(7) (as such section was in effect on January 27, 2008) of title 28, United States Code; or

2. Be a U.S. person who was taken and held hostage from the United States Embassy in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, if such person is identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia; or

3. Be the spouse or child of a former hostage described in Part III.2 and identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia; or

4. Be the Personal Representative of deceased individual(s) described in Part III.1 to Part III.3.

In no event shall an individual who is criminally culpable for an act of international terrorism receive any compensation from the Fund, either directly or indirectly on behalf of a victim. *See* 42 U.S.C. 10609(h).

Part IV. Supporting Documentation

An applicant must submit the following supporting documents, as applicable. Any requests for waiver of a documentation requirement or an extension of time in which to submit a particular document must be submitted to the Special Master in writing at least 20 business days prior to the application deadline set forth in Part VIII below. Decisions to waive a documentation requirement or to extend the time to submit a particular document are wholly within the discretion of the Special Master. Failure to submit all required documentation by the application deadline may result in delay of the adjudication of or denial of the application.

1. An applicant who seeks to establish eligibility for payment on the basis of a final judgment described in Part III.1 above must submit:

a. A copy of the final judgment; and

b. A list identifying any immediate family member(s) of the applicant who is/are also identified in the final judgment described in Part III.1 above.

2. An applicant who seeks to establish eligibility for payment on the basis described in Part III.2 above must submit:

a. If seeking payment as a person who was held hostage in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, verification of the date on which he or she was taken hostage from the United States Embassy in Tehran, Iran, and the date on which he or she was released, as well as verification that he or she is a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia.

b. If seeking payment as the spouse of a person who was held hostage in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, a copy of a marriage certificate showing the date of marriage and an affirmation that the marriage continued through January 20, 1981, as well as verification that he or she is a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia.

c. If seeking payment as the child of a person who was held hostage in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, a copy of a birth certificate or adoption decree showing a date of birth or adoption prior to January 20, 1981, as well as verification that he or she is a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia.

3. Personal Representatives must show sufficient evidence of their authority to represent the estate of a decedent by submitting copies of relevant legal documentation, such as court orders; letters testamentary or similar documentation; proof of the purported Personal Representative's relationship to the decedent; and copies of wills, trusts, or other testamentary documents.

4. Any other information that the Special Master deems necessary to determine the applicant's eligibility.

Part V. Collateral Sources Information

The Act requires that an applicant identify compensation from any source other than this Fund that the applicant, or the applicant's beneficiaries, has/have received or is/are entitled or scheduled to receive as a result of the act of international terrorism that gave rise to his or her final judgment. The applicant shall provide information and documentation regarding the amount, nature, and source of any payment received or entitled or scheduled to receive, and must update that information throughout the period of the Fund.

Part VI. Special Procedures for Judgment Creditors in Peterson V. Iran and for Settling Judgment Creditors in In Re 650 Fifth Avenue & Related Properties

1. *Election to Participate in Fund.* By September 12, 2016, a United States person who is a judgment creditor in the proceedings captioned *Peterson* v. *Islamic Republic of Iran,* No. 10 Civ. 4518 (S.D.N.Y.), or a Settling Judgment Creditor as identified in the order dated May 27, 2014, in the proceedings captioned *In re 650 Fifth Avenue & Related Properties,* No. 08 Civ. 10934 (S.D.N.Y. filed Dec. 17, 2008), shall notify the Special Master in writing of his or her election to participate in the Fund, and shall acknowledge in writing that, by so electing, he or she irrevocably assigns to the Fund all rights, title, and interest in such person's claims to the assets at issue in the identified proceedings.

2. *Applications for Conditional Payment.* A United States person who is a judgment creditor or a Settling Judgment Creditor in the proceedings identified in Part VI.1 who does not elect to participate in the Fund may, notwithstanding such failure to elect, submit an application for conditional payment from the Fund, subject to the limitations and exceptions set forth in the Act and the application requirements set forth in this Notice.

Part VII. Procedures for Personal Representatives

1. *In general.* For any deceased applicant, the Personal Representative shall be:

a. An individual appointed by a court of competent jurisdiction as the Personal Representative of the decedent or as the executor or administrator of the deceased applicant's will or estate; or

b. In the event that no Personal Representative or executor or administrator has been appointed by any court of competent jurisdiction, and such issue is not the subject of pending litigation or other dispute, the Personal Representative for purposes of compensation by the Fund is the person named by the deceased applicant in his or her will as the executor or administrator of the deceased applicant's estate; or

c. In the event no will exists, the Personal Representative for purposes of compensation by the Fund is the first person in the line of succession established by the laws of the deceased applicant's domicile governing intestacy or, in limited circumstances, the Special Master may, at his discretion, determine the Personal Representative for purposes of compensation by the Fund.

2. *Notice to beneficiaries.*

a. Any purported Personal Representative must, before filing a claim, provide written notice of the claim to the immediate family of the decedent; to the executor, administrator, and beneficiaries of the decedent's will; and to any other persons who may reasonably be expected to assert an interest in an award or to have a cause of action to recover damages relating to the wrongful death of the decedent.

b. Personal delivery or transmission by certified mail, return receipt requested, shall be deemed sufficient notice under this Part. The purported Personal Representative must certify that such notice (or other notice that the Special Master deems appropriate) has been given.

3. *Objections to Personal Representatives.* Objections to the authority of an individual to file as the Personal Representative of a decedent may be filed with the Special Master by parties who assert a financial interest in the award up to 30 days following receipt of notice by the Personal Representative under Part VII.2. If timely filed, such objections shall be treated as evidence of a "dispute" under section (4) of this Part.

4. *Disputes as to Identity.* The Special Master will not, and shall not be required to, arbitrate, litigate, or otherwise resolve any dispute as to the identity of the Personal Representative. In the event of a dispute over the appropriate Personal Representative, the Special Master may suspend adjudication of the claim or, if sufficient information is provided, calculate the appropriate award and authorize payment, but withhold any payment until the dispute is resolved either by agreement of the disputing parties or by a court of competent jurisdiction. Alternatively, the disputing parties may agree in writing to the identity of a Personal Representative to act on their behalf, who may seek and accept payment from the Fund while the disputing parties work to settle their dispute.

5. *Foreign Claims.* In the case of claims brought by a foreign citizen on behalf of a deceased applicant, the Special Master may alter the requirements for documentation set forth in Part IV.3 and Part VII.

Part VIII. Application Deadlines

1. Applications based on a judgment described in Part III.1 above that was a final judgment before the date of publication of this Notice and applications based on the statement described in Part III.2 to Part III.4 above must be submitted by October 12, 2016.

2. Applications based on a judgment described in Part III.1 that was final on or after the date of publication of this Notice must be submitted not later than 90 days after the date of obtaining a final judgment.

3. For good cause shown, the Special Master may grant a reasonable extension of a deadline under this Part. Any request for such an extension must be made in writing and must describe the

circumstances that the applicant believes constitute good cause.

4. The Special Master shall determine the timeliness of all claims.

Part IX. Award of Compensation to Informers

If an applicant is seeking additional compensation as an informer, as described in 42 U.S.C. 10609(g)(2)(a), the applicant must identify, and notify the Attorney General in writing by contacting the Chief, Asset Forfeiture and Money Laundering Section, Criminal Division, Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20530–0001, of funds or property of a state sponsor of terrorism, or held by a third party on behalf of or subject to the control of that state sponsor of terrorism. *See* 42 U.S.C. 10609(g)(1).

Part X. Request for a Hearing

An applicant may request a hearing regarding the Special Master's denial of the claim in whole or in part no later than 30 days after receipt of the Special Master's written decision.

1. Hearings shall be before the Special Master or his designee. All hearings will be closed to the public.

2. Based on the circumstances of the claim, the Special Master or his designee shall determine the time, location, duration, and procedures for the hearing.

3. The Special Master shall notify the applicant in writing of his final decision affirming or amending the original decision within 90 days of the hearing, but need not create or provide any written record of the deliberations that resulted in that determination. There shall be no further review or appeal of the Special Master's determination. *See* 42 U.S.C. 10609(b)(3)(B).

Part XI. Signatures and Certifications

An application will be deemed submitted when it is submitted online at *www.usvsst.com,* emailed to *info@usvsst.com,* faxed toll-free for domestic callers at (855) 409–7130 and for international callers at (614) 553–1426, or if mailed or overnight mailed, by the postmark date. By submitting the application, the applicant (or if submitted through counsel, both applicant and counsel) acknowledges and certifies as to each of the following:

1. *Veracity of Application.* The applicant certifies, under oath, subject to penalty of perjury or in a manner that meets the requirements of 28 U.S.C. 1746, that the information provided in the application and any documents submitted in support of the claim are true and accurate to the best of the applicant's knowledge, and the applicant agrees that any payment made by the Fund is expressly conditioned upon the truthfulness and accuracy of the information and documentation submitted in support of the claim. Where an applicant is represented by a third party, such as an applicant's legal guardian, the Personal Representative of the deceased applicant's estate, or other personal legally authorized to act for the applicant, these persons must have authority to certify on behalf of the applicant.

2. *Potential Criminal Penalties.* The applicant understands that false statements or claims made in connection with the application may result in fines, imprisonment and/or any other remedy available by law to the Federal Government, including as provided in 18 U.S.C. 1001, and that claims that appear to be potentially fraudulent or to contain false information will be forwarded to federal, state, and local law enforcement authorities for possible investigation and prosecution.

3. *Limitation on Attorneys' Fees.* If an applicant is represented by counsel, no attorney shall charge, receive, or collect, and the Special Master will not approve, any payment of fees and costs that in the aggregate exceeds 25 percent of any payment made under the Act on such claim.

4. *Subrogation of Rights.* If the applicant receives payment under the Act, the applicant agrees and accepts that the United States shall be subrogated to the rights of the applicant (and any of his heirs, successors, or assigns) to the extent and in the amount of such payment, but that, to the extent amounts of damages remain unpaid and outstanding to the applicant following any payments made under this Act, each applicant shall retain that applicant's creditor rights in any unpaid or outstanding amounts of the judgment, including any prejudgment or post-judgment interest, or punitive damages, awarded by a United States district court pursuant to a judgment.

5. *Conditional Payment.* If the applicant is seeking a conditional payment pursuant to Part VI above, the applicant understands that, notwithstanding the applicant's eligibility for payment and the deadline for initial payments set forth in the Act, the Special Master shall allocate but withhold payment to such applicant until such time as an adverse final judgment is entered in both of the proceedings identified in Part VI.

Dated: July 8, 2016.

Kenneth Feinberg,

Special Master.

[FR Doc. 2016–16672 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 06–2016]

Privacy Act of 1974; Systems of Records

AGENCY: Criminal Division, United States Department of Justice.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, 5 U.S.C. 552a, and Office of Management and Budget (OMB) Circular No. A–130, notice is hereby given that the Criminal Division (CRM), a component within the United States Department of Justice (Department or DOJ), is establishing a new system of records as noted below to process applications filed by individuals seeking compensation from the United States Victims of State Sponsored Terrorism Fund.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice will become effective upon publication, subject to a 30-day comment period for the routine uses claimed in the "ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM" section of this systems of records notice. Therefore, please submit any comments regarding the described routine uses by August 15, 2016.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments to the Department of Justice, ATTN: Privacy Analyst, Office of Privacy and Civil Liberties, Department of Justice, National Place Building, 1331 Pennsylvania Avenue NW., Suite 1000, Washington, DC 20530, or by facsimile at 202–307–0693. To ensure proper handling, please reference the above-listed CPCLO Order No. on your correspondence.

FOR FURTHER INFORMATION CONTACT: Amanda Marchand Jones, Chief, FOIA/PA Unit, Criminal Division, Suite 1127 Keeney Building, NW., Washington, DC 20530, or by facsimile at 202–514–6117.

SUPPLEMENTARY INFORMATION: The Justice for United States Victims of State Sponsored Terrorism Act (Act), passed as part of the Consolidated Appropriations Act of 2016, Public Law 114–113, mandated the establishment of the United States Victims of State Sponsored Terrorism Fund (Fund). Pursuant to the Act, the Fund may compensate eligible United States persons who (1) hold a final judgment issued by a United States district court awarding the applicant compensatory damages arising from acts of international terrorism for which a foreign state sponsor of terrorism was found not immune from the jurisdiction of the courts of the United States under the Foreign Sovereign Immunities Act; or (2) were taken and held hostage from the United States Embassy in Tehran, Iran, during the period beginning November 4, 1979, and ending January 20, 1981, or are spouses and children of these hostages, if also identified as a member of the proposed class in case number 1:00–CV–03110 (EGS) of the United States District Court for the District of Columbia. In order to establish eligibility for compensation, claimants must provide sufficient information for a determination by the Special Master for the USVSST Fund, of whether they are eligible, and if so, what amount of compensation. The Act also mandates collection of information regarding other sources of compensation related to the judgment which may modify the amount of compensation. This system of records is being established to enable the prompt adjudication of these claims.

Elsewhere in the **Federal Register**, the Department has provided the eligibility requirements and procedures for the submission and consideration of applications to the Fund. More detailed information regarding the Fund, including answers to frequently asked questions, is available on the U.S. Victims of State Sponsored Terrorism Web site at *www.usvsst.com.*

In accordance with 5 U.S.C. 552a(r), the Department is providing a report to OMB and Congress on the new systems of records.

Dated: July 8, 2016.

Erika Brown Lee,

Chief Privacy and Civil Liberties Officer, United States Department of Justice.

Justice/CRM–029

SYSTEM NAME:

United States Victims of State Sponsored Terrorism Fund (USVSSTF) File System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records in this system are located at: U.S. Department of Justice, Criminal Division, 950 Pennsylvania Avenue NW., Washington, DC 20530; Federal Records Center, Suitland, MD 20409, 5151 Blazer Parkway, Suite A, Dublin, OH 43017; and 1985 Marcus Avenue, Suite 200, Lake Success, NY 11042.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system covers: Those individuals claiming eligibility for compensation from the United States Victims of State Sponsored Terrorism Fund, including the personal representative of any decedent's estate, or legal counsel representing the claimant; and those DOJ employees, including contractors, that are administering, assessing, and adjudicating the claims.

CATEGORIES OF RECORDS IN THE SYSTEM:

Application forms filed by or on behalf of claimants seeking benefits under the Fund; documentation submitted in support of claims; legal, personal, financial, insurance, tax, and other records obtained or generated to assess, adjudicate, and pay claims.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Justice for United States Victims of State Sponsored Terrorism Act, enacted into law as Title IV, Division O, section 404 of the Consolidated Appropriations Act, 2016, Public Law 114–113, codified at 42 U.S.C. 10609 (2015).

PURPOSE(S):

These records are collected or generated for the purpose of determining eligibility of and compensation to claimants under the United States Victims of State Sponsored Terrorism Act.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record maintained in this system of records may be disseminated as a routine use of records as follows:

(a) To the Department of Treasury to ensure that any recipients of federal payments who also owe delinquent federal debts have their payment offset or withheld or reduced to satisfy the debt.

(b) Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

(c) In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the Department of Justice determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

(d) To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion of such matters as settlement, plea bargaining, or in informal discovery proceedings.

(e) To the news media and the public, including disclosures pursuant to 28 CFR 50.2, unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

(f) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

(g) To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

(h) To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

(i) To appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(j) To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in a hard-copy, paper format in filing cabinets in a secure room. Electronic data is stored in electronic media via a configuration of client/servers and personal computers. Records are stored in accordance with applicable executive orders, statutes, and agency implementing regulations.

RETRIEVABILITY:

Files and automated data are retrieved by name of a claimant, the personal representative, or legal counsel of a claimant, claim number, Social Security Number and/or Tax Identification Number.

SAFEGUARDS:

Information in this system is maintained in accordance with applicable laws, rules, and policies on protecting individual privacy. Access to the servers storing electronic data and the backup tapes is controlled by a card-key security system with access provided only to appropriate personnel. Backup tapes stored offsite are maintained in accordance with a government contract that requires adherence to applicable laws, rules, and policies on protecting individual privacy. Internet connections are protected by multiple firewalls. Security personnel conduct periodic vulnerability scans to ensure security compliance and access reviews are conducted on a regular basis. User access requires two factor RSA authentication and user access is determined by the minimal amount of user authorization necessary to complete their job. Paper records are maintained in a secure room.

RETENTION AND DISPOSAL:

Records are to be retained and disposed of in accordance with agency retention plans.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Attorney General, Criminal Division, U.S. Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20503–0001.

NOTIFICATION PROCEDURE:

Same as "RECORD ACCESS PROCEDURES," below.

RECORD ACCESS PROCEDURES:

All requests for access must be in writing and should be addressed to: Chief, FOIA/PA Unit, Criminal Division, Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20530–0001 or *crm.foia@usdoj.gov*. The communication should be clearly marked "Privacy Act Access Request." The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury.

Although no specific form is required, you may obtain forms for this purpose from the FOIA/Privacy Act Mail Referral Unit, Justice Management Division, United States Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20530–0001, or on the Department of Justice Web site at *http://www.justice.gov/oip/oip-request.html.*

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend information maintained in the system should direct their requests to the address indicated in the "RECORD ACCESS PROCEDURES" section, above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. The communication should be clearly marked "Privacy Act Amendment Request."

RECORD SOURCE CATEGORIES:

Individuals or entities having information pertinent to the adjudication of compensation claims, including but not limited to: Injured individuals; personal representatives of deceased individuals; eligible claimants; family members; physicians and other medical professionals, hospitals, and clinics; insurers, employers, and their agents and representatives.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2016–16670 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

[Docket No. ODAG 163]

Notice of Public Comment Period on Revised Federal Advisory Committee Work Products

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: This notice announces the opening of the comment period on revised subcommittee draft work products of the National Commission on Forensic Science.

DATES: Written public comment regarding revised subcommittee draft work products of the National Commission on Forensic Science meeting materials should be submitted through *www.regulations.gov* before August 15, 2016.

FOR FURTHER INFORMATION CONTACT: Jonathan McGrath, Ph.D., Senior Policy Analyst at the National Institute of Justice and Designated Federal Official, 810 7th Street NW., Washington, DC 20531, by email at *Jonathan.McGrath@usdoj.gov* by phone at (202) 514–6277.

SUPPLEMENTARY INFORMATION: On May 26, 2016, the Department of Justice published in the **Federal Register** a Notice announcing the June 20–21, 2016, Federal Advisory Committee Meeting of the National Commission on Forensic Science (81 FR 33550). During the Commission proceedings on June 20–21, 2016, subcommittees were provided an opportunity to revise existing draft work products. This Notice announces a public comment period to provide an opportunity for submitting comments for the revised work products.

Pursuant to section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written comments to the Commission in response to the revised draft work products. Work products are available on the Commission's Web site: *http://www.justice.gov/ncfs/work-products* and on *www.regulations.gov.*

Dated: July 7, 2016.

Victor W. Weedn,

Senior Forensic Advisor to the Deputy Attorney General, U.S. Department of Justice.

[FR Doc. 2016–16682 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *The Bear's Club Founding Partners, Ltd., et al.,* No. 9:15–cv–81466–WPD, was lodged with the United States District Court for the Southern District of Florida on July 7, 2016.

The proposed Consent Decree concerns a complaint filed by the United States, on behalf of the United States Army Corps of Engineers, against The Bear's Club Founding Partners, Ltd., The Bear's Club Development Co., The Bear's Club Builders LLC, Bear's Club Management Corp., Clarendon Properties Group, Inc., Ivan Charles Frederickson, Ira Fenton, and Robert B. Whitley to obtain a civil penalty and other appropriate relief for violating section 404 of the Clean Water Act, 33 U.S.C. 1344, by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations against the foregoing Defendants by directing them to pay a civil penalty. The Defendants have already completed mitigation sufficient to offset the loss of aquatic resources caused by the alleged violations.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Carlos J. Raurell, Assistant United States Attorney for the United States Attorney's Office for the Southern District of Florida, and Andrew J. Doyle, Senior Attorney for the United States Department of Justice, Environment and Natural Resources Division, P.O. Box 7611, Washington, DC 20044 and refer to *United States* v. *The Bear's Club Founding Partners, Ltd., et al.,* DJ #90–5–1–1–20788.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Southern District of Florida, 400 North Miami Avenue, Miami, FL 33128. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/Consent_Decrees.html.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2016–16597 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1121—NEW]

Agency Information Collection Activities; Proposed Collection Comments Requested;

New collection: Survey of State Criminal Investigative Agencies on Law Enforcement Use of Force

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 27475, on May 6, 2016, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until August 15, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Shelley Hyland, Statistician, Law Enforcement Statistics, Bureau of Justice Statistics, 810 Seventh Street NW., Washington, DC 20531 (email: *Shelley.Hyland@usdoj.gov;* telephone: 202–616–1706). Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *The Title of the Form/Collection:* Survey of State Criminal Investigative Agencies on Law Enforcement Use of Force.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* No agency form number at this time. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will be state criminal investigative agencies (SCIAs). *Abstract:* The President's Task Force on 21st Century Policing called for law enforcement agencies to use external and independent criminal investigation of use of force incidents. In some states, the criminal investigative agency serves as the primary body that local and county law enforcement agencies use as the independent investigator. However, it is currently unknown how common this is nationwide. This survey will be administered to all state criminal investigative agencies (SCIAs) in order to determine the extent to which SCIAs are investigating use of force cases for other law enforcement agencies. SCIAs will be asked about the types of use of force incidents investigated and the jurisdictions covered within the state. The survey will also assess how SCIAs become involved in these investigations, how cases are closed, the data systems that SCIAs use to record and report on use of force investigations, and the total number of law enforcement use of force cases investigated in a three year period.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An agency-level survey will be sent to a representative at all 49 SCIAs. The expected burden placed on these

respondents is about 53 minutes per respondent.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total respondent burden is approximately 44 burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: July 11, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–16641 Filed 7–13–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Certification by School Official

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, "Certification by School Official," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before August 15, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201601-1240-012* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Certification by School Official information collection. In order to qualify as an eligible dependent for black lung benefits, a child aged 18- to 23-years must be a full-time student as described in the Black Lung Benefits Act, 30 U.S.C. 901 *et. seq.,* and regulations 20 CFR 725.209. A school official completes a Certification by School Official (Form CM–981) to verify whether a Black Lung beneficiary's dependent between the ages of 18 to 23 years qualifies as a full-time student. This information collection has been classified as a revision, because of questions added to Form CM–981 that provide clearer language on what information the school registrars need to provide, *i.e.* contact information and expected graduation date and because of formatting changes. Black Lung Benefits Act section 426 authorizes this information collection. *See* 30 U.S.C. 936.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0031. The current approval is scheduled to expire on July 31, 2016; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 21, 2016 (81 FR 3477).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0031. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Certification by School Official.

OMB Control Number: 1240–0031.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 493.

Total Estimated Number of Responses: 493.

Total Estimated Annual Time Burden: 82 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: July 7, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–16681 Filed 7–13–16; 8:45 am]

BILLING CODE 4510–XCK–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; Federal Credit Union Bylaws

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: NCUA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on an extension of a previously approved collection, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Written comments should be received on or before September 12, 2016 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314; Fax No. 703–519–8579; or Email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the address above.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0052.

Title: Federal Credit Union Bylaws.

Abstract: Section 108 of the Federal Credit Union (FCU) Act (12 U.S.C. 1758) requires the National Credit Union Administration (NCUA) Board to prepare bylaws before an FCU's charter is complete. The form bylaws are established to simplify the organization of a FCU and establish uniformity regarding FCU operations and member rights. The NCUA Board adopted the Bylaws and incorporated them into NCUA's regulations at 12 CFR 701.2 and as Appendix A to Part 701, in 2007. The bylaws address a broad range of matters concerning: An FCU's organization and governance; the FCU's relationship to members; and the procedures and rules an FCU follows. The NCUA uses the information both to regulate FCUs to protect consumers and monitor their safety and soundness to protect the National Credit Union Share Insurance Fund.

Type of Review: Extension of a previously approved collection.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents/Recordkeepers: 3,721 Federal Credit Unions.

Estimated Annual Frequency: 337.

Estimated Annual No. of Responses: 1,255,046.

Estimated Burden Hours per Response: 0.35.

Estimated Total Annual Burden Hours: 436,614.

Adjustment are being made to reflect the continuing decline in the number of FCUs and also an increase in the burden associated with the recordkeeping required due to the complexity of credit union operations and the corresponding committee minutes required to document such operations.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on July 11, 2016.

Dated: July 11, 2016.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2016–16654 Filed 7–13–16; 8:45 am]

BILLING CODE 7535–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2015–114; MC2016–164 and CP2016–238; MC2016–165 and CP2016–239; MC2016–166 and CP2016–240; MC2016–167 and CP2016–241]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 18, 2016 (Comment due date applies to all Docket Nos. listed above).

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2015–114; *Filing Title:* Notice of United States Postal Service of Change in Prices Pursuant to Amendment to Priority Mail & First-Class Package Service Contract 7; *Filing Acceptance Date:* July 8, 2016; *Filing Authority:* 39 CFR 3015.5 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* July 18, 2016.

2. *Docket No(s).:* MC2016–164 and CP2016–238; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express Contract 39 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* July 8, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* July 18, 2016.

3. *Docket No(s).:* MC2016–165 and CP2016–239; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 21 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* July 8, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Curtis E. Kidd; *Comments Due:* July 18, 2016.

4. *Docket No(s).:* MC2016–166 and CP2016–240; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 22 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* July 8, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Curtis E. Kidd; *Comments Due:* July 18, 2016.

5. *Docket No(s).:* MC2016–167 and CP2016–241; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 23 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* July 8, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* July 18, 2016.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–16690 Filed 7–13–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 8, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail & First-Class Package Service Contract 22 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–166, CP2016–240.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–16633 Filed 7–13–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 8, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail & First-Class Package Service Contract 21 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–165, CP2016–239.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–16631 Filed 7–13–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 8, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail & First-Class Package Service Contract 23 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–167, CP2016–241.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–16634 Filed 7–13–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 8, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail Express Contract 39 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–164, CP2016–238.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–16630 Filed 7–13–16; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Sunshine Act; Notice of Public Meeting

Notice is hereby given that the Railroad Retirement Board will hold a closed meeting on July 28, 2016 beginning at 10:00 a.m. at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois 60611. The agenda for this meeting follows:

Closed meeting notice:

(1) Chief Financial Officer Position

The person to contact for more information is Martha P. Rico, Secretary to the Board, Phone No. 312–751–4920.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2016–16765 Filed 7–12–16; 4:15 pm]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78264; File No. SR-BatsBZX–2016–35]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the JPMorgan Global Bond Opportunities ETF

July 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade shares of the JPMorgan Global Bond Opportunities ETF (the "Fund") of the J.P. Morgan Exchange-Traded Fund Trust (the "Trust") under BZX Rule 14.11(i) ("Managed Fund Shares"). The shares of the Fund are collectively referred to herein as the "Shares."

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange.[3] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange. The Fund will be an actively managed fund. The Shares will be offered by the Trust, which was established as a Delaware statutory trust on February 25, 2010. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement with respect to the Fund on Form N–1A ("Registration Statement") with the Commission.[4]

Description of the Shares and the Fund

J.P. Morgan Investment Management Inc. will be the investment adviser ("JPMIM" or "Adviser") to the Fund. The Adviser will serve as the administrator for the Fund (the "Administrator"). SEI Investments Distribution Co. (the "Distributor") serves as the distributor for the Trust. JPMorgan Chase Bank, N.A. will act as the custodian (the "Custodian") and transfer agent ("Transfer Agent") for the Trust.

BZX Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a "fire wall" between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[5] In addition, Rule 14.11(i)(7) further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. Rule 14.11(i)(7) is similar to BZX Rule 14.11(b)(5)(A)(i), however, Rule 14.11(i)(7) in connection with the establishment of a "fire wall" between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not registered as a broker-dealer but the Adviser is affiliated with a broker-dealer and has implemented a "fire wall" with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio. In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission approved BZX Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[4] *See* Registration Statement on Form N–1A for the Trust, dated May 26, 2016 (File Nos. 333–191837 and 811–22903). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a–1) ("1940 Act") (the "Exemptive Order"). *See* Investment Company Act Release No. 31990 (February 9, 2016) (File No. 812–13761).

[5] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the "Advisers Act"). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

JPMorgan Global Bond Opportunities ETF

According to the Registration Statement, the Fund will seek to provide total return by investing across sectors in developed and emerging markets located around the world. The Fund is an actively-managed fund that does not seek to replicate the performance of a specified index. Because the Fund is not managed to a benchmark, the Adviser has broad discretion to shift the Fund's exposure to strategies, sectors, countries or currencies based on changing market conditions and its view of the best mix of investment opportunities. In buying and selling investments for the Fund, the Adviser allocates the Fund's exposure to strategies, sectors, countries and currencies based on the Adviser's analysis of individual investments and broader economic conditions in individual countries, regions and the world. This allows the Adviser to take a conservative approach during uncertain periods and move into higher risk opportunities as market conditions improve, which may result in the Fund focusing in only a few markets and sectors.

Under normal circumstances, the Fund will invest at least 80% of its net assets (plus the amount of borrowings for investment purposes) ("Assets") in bonds. Under normal circumstances, the Fund will invest at least 40% of its Assets in countries other than the United States. The Fund may invest in developed or emerging markets. Emerging markets currently includes most countries in the world except Australia, Canada, Japan, New Zealand, the U.S., the United Kingdom and most western European countries and Hong Kong. In managing the Fund, the Adviser will seek to diversify the Fund's portfolio by investing in issuers in at least three countries other than the U.S. The Fund may invest a substantial part of its assets in just one country and is not required to allocate its investments in any set percentages in any particular countries.

Although the Fund has the flexibility to invest without limit in securities that are rated below investment grade (also known as junk bonds or high yield securities), or the unrated equivalent, the Fund generally invests at least 25% of the Fund's Assets in securities that at the time of purchase are rated investment grade or the unrated equivalent. The Fund has flexibility to decrease the percentage of Assets invested in investment grade securities at any time to take advantage of higher risk opportunities when market conditions are improving.

The Fund currently seeks to maintain a duration of eight years or less, although the Fund has the flexibility to maintain a longer duration under certain market conditions such as significant volatility in interest rates and spreads. Duration is a measure of the price sensitivity of a debt security or a portfolio of debt securities to relative changes in interest rates. For instance, a duration of three years means that a security's or portfolio's price would be expected to decrease by approximately 3% with a 1% increase in interest rates (assuming a parallel shift in yield curve).

As part of its principal investment strategy and for temporary defensive purposes, any portion of the Fund's total assets may be invested in cash and cash equivalents.

Principal Holdings

The Fund intends to achieve its investment objective by investing, under normal circumstances,[6] 80% of its Assets in bonds (a debt security with a maturity of 90 days or more at the time of its issuance) ("Bonds"), subject to certain limits described below. For purposes of this filing, Bonds will be defined as the following instruments: Asset-backed securities [7] (including mortgages,[8] mortgage dollar rolls,[9] and stripped mortgage-backed securities); [10] bank obligations; commercial paper; [11] convertible bonds; corporate debt securities; [12] inflation-linked debt securities; inverse floating rate instruments; [13] municipal securities; [14]

---

[6] The term "under normal circumstances" includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[7] Asset-backed securities ("ABS") include securities secured by company receivables, home equity loans, truck and auto loans, leases, and credit card receivables or other securities backed by other types of receivables or other assets. ABS includes mortgage-backed securities ("MBS"), which are debt obligations secured by real estate loans and pools of loans such as collateralized mortgage obligations ("CMOs"), commercial mortgage-backed securities ("CMBS"), and other asset-backed structures. The Fund may not invest more than 20% of its portfolio in a combination of: Illiquid ABS (as determined in footnote 31, below), and distressed or defaulted loans, including non-performing loans and reperforming loans.

[8] Mortgages are debt instruments secured by real property and include adjustable rate mortgage loans ("ARMs"), which are loans in a mortgage pool which provide for a fixed initial mortgage interest rate for a specified period of time, after which the rate may be subject to periodic adjustments.

[9] Mortgage dollar rolls involve a transaction in which the Fund sells securities for delivery in a current month and simultaneously contracts with the same party to repurchase similar but not identical securities on a specified future date.

[10] Stripped mortgage-backed securities are securities which are usually structured with two classes of shares that receive different proportions of the interest and principal from a pool of mortgage assets. These include Interest-Only ("IO") and Principal-Only ("PO") securities issued outside a Real Estate Mortgage Investment Conduit ("REMIC") or CMO structure.

[11] Secured and unsecured short-term promissory notes issued by corporations and other entities. Maturities generally vary from a few days to nine months.

[12] May include bonds and other debt securities of domestic and foreign issuers, including obligations of industrial, utility, banking and other corporate issuers [sic]. While the Fund is permitted to invest without restriction in corporate bonds, the Adviser expects that, under normal circumstances, the Fund will generally seek to invest in corporate bond issuances that have at least $100,000,000 par amount outstanding. Further, component corporate bonds that in the aggregate account for at least 75% of the weight of corporate bonds will have a minimum original principal outstanding of $100 million or more.

[13] Inverse floating rate instruments are leveraged variable debt instruments with interest rates that reset in the opposite direction from the market rate of interest to which the inverse floater is indexed.

[14] Municipal securities held by the Fund will be rated Baa3/BBB- or higher by at least two of the following ratings agencies if all three agencies rate the security: Moody's, S&P and Fitch. If only two of the three agencies rate the security, the lower rating is used. If only one of the three agencies rates a security, the rating must be at least Baa3/BBB-. Municipal securities held by the Fund will have an outstanding par value of at least $7 million and be issued as part of a transaction of at least $75 million.

obligations of supranational agencies; private placements, restricted securities, and other unregistered securities; securities issued in connection with reorganizations and corporate restructurings; sovereign obligations; structured investments;[15] treasury receipts;[16] trust preferreds; U.S. Government Agency Securities;[17] U.S. Government obligations;[18] and zero-coupon, pay-in-kind, and deferred payment securities.[19] Bonds may have fixed or variable interest rates[20] and be of any maturity.

In addition to investing at least 80% of its Assets in Bonds, the Fund may also invest in the following instruments as part of its principal investment strategy ("Non-Bonds"): Custodial receipts;[21] derivatives, including options,[22] swaps,[23] and futures; exchange traded funds ("ETFs");[24] foreign currency transactions;[25] investment company securities that are not ETFs;[26] preferred stock; and short-term funding agreements.[27]

Other Portfolio Holdings

While the Adviser, under normal circumstances, will invest at least 80% of the Fund's Assets in Bonds and may invest additionally in Non-Bonds described above as part of its principal investment strategy, the Adviser may invest up to 20% of the Fund's Assets in other securities and financial instruments, as described below.

The Fund may invest in auction rate securities, which include auction rate municipal securities and auction rate preferred securities issued by closed-end investment companies.

The Fund may invest in Brady Bonds, which are securities created through the exchange of existing commercial bank loans to sovereign entities for new obligations in connection with a debt restructuring.

The Fund may invest in commodity-related pooled investment vehicles, which include only the following instruments: Trust Issued Receipts (as defined in BATS Rule 14.11(f)); Commodity-Based Trust Shares (as defined in Rule 14.11(e)(4)); Currency Trust Shares (as defined in Rule 14.11(e)(5)); Commodity Index Trust Shares (as defined in Rule 14.11(e)(6)); Trust Units (as defined in Rule 14.11(e)(9)); and Paired Class Shares (as defined in NASDAQ Stock Market LLC Rule 5713). The Fund will not invest in inverse or leveraged (*e.g.,* 2X, –2X, 3X or –3X) commodity-related pooled investment vehicles pooled investment vehicles.

The Fund may invest in commodity-linked derivatives, which are derivatives for which the value derives from the price of a commodity, including commodity futures and commodity options.

The Fund may invest in U.S. equity securities. Equity securities are securities that represent an ownership interest (or the right to acquire such an interest) in a company and include common and preferred stock, warrants, and rights. The Fund's investments in such U.S. equity securities may include securities traded over-the-counter as well as those traded on a securities exchange. The Fund may purchase such securities on a forward commitment or when-issued or delayed delivery basis, which means delivery and payment take place a number of days after the date of the commitment to purchase.

The Fund may purchase exchange-traded common stocks, exchange-traded warrants, and exchange-traded rights in foreign corporations. The Fund's investments in common stock of foreign corporations may also be in the form of American Depositary Receipts ("ADRs"), Global Depositary Receipts ("GDRs") and European Depositary Receipts ("EDRs") (collectively "Depositary Receipts").[28]

---

[15] A structured investment is a security having a return tied to an underlying index or other security or asset class. Structured investments generally are individually negotiated agreements and may be traded over-the-counter. Structured investments are organized and operated to restructure the investment characteristics of the underlying security.

[16] The Fund may purchase interests in separately traded interest and principal component parts of U.S. Treasury obligations that are issued by banks or brokerage firms and that are created by depositing U.S. Treasury notes and U.S. Treasury bonds into a special account at a custodian bank. Receipts include Treasury Receipts ("TRs"), Treasury Investment Growth Receipts ("TIGRs"), and Certificates of Accrual on Treasury Securities ("CATS").

[17] U.S. Government Agency Securities include securities issued by agencies and instrumentalities of the U.S. government. These include all types of securities issued by the Government National Mortgage Association ("Ginnie Mae"), the Federal National Mortgage Association ("Fannie Mae") and the Federal Home Loan Mortgage Corporation ("Freddie Mac"), including funding notes, subordinated benchmark notes, CMOs and REMICs.

[18] U.S. Government obligations include direct obligations of the U.S. Treasury, including Treasury bills, notes and bonds, all of which are backed as to principal and interest payments by the full faith and credit of the United States, and separately traded principal and interest component parts of such obligations that are transferable through the Federal book-entry system known as Separate Trading of Registered Interest and Principal of Securities ("STRIPS") and Coupons Under Book Entry Safekeeping ("CUBES").

[19] Zero-coupon securities are securities that are sold at a discount to par value and on which interest payments are not made during the life of the security. Pay-in-kind securities are securities that have interest payable by delivery of additional securities. Deferred payment securities are zero-coupon debt securities which convert on a specified date to interest bearing debt securities.

[20] A variable rate security provides for the automatic establishment of a new interest rate on set dates. Variable rate obligations whose interest is readjusted no less frequently than annually will be deemed to have a maturity equal to the period remaining until the next readjustment of the interest rate. The Fund may also purchase floating rate securities. A floating rate security provides for the automatic adjustment of its interest rate whenever a specified interest rate changes. Interest rates on these securities are ordinarily tied to, and are a percentage of, a widely recognized interest rate, such as the yield on 90-day U.S. Treasury bills or the prime rate of a specified bank. These rates may change as often as twice daily.

[21] The Fund may acquire securities in the form of custodial receipts that evidence ownership of future interest payments, principal payments or both on certain U.S. Treasury notes or bonds in connection with programs sponsored by banks and brokerage firms. These are not considered to be U.S. government securities. These notes and bonds are held in custody by a bank on behalf of the owners of the receipts.

[22] The Fund may invest in OTC and exchange-traded call and put options, including only the following: Fixed income securities, currencies, and indexes of fixed income, currencies, or credit default swaps. All options will be covered.

[23] The Fund may invest in swaps, including only the following: Interest rate swaps, credit default swaps, currency swaps, and total return swaps.

[24] For purposes of this filing, ETFs include Index Fund Shares (as described in Rule 14.11(c)); Portfolio Depositary Receipts (as described in Rule 14.11(b)); and Managed Fund Shares (as described in Rule 14.11(i)). The ETFs all will be listed and traded in the U.S. on registered exchanges. The Fund may invest in the securities of ETFs registered under the 1940 Act consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation or order of the Commission or interpretation thereof. The Fund will not invest in inverse or leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

[25] Foreign currency transactions will be used to hedge against currency risks, for other risk management purposes, to increase income or gain to the Fund, and/or for other investment purposes and, in addition to the derivative strategies described above, may include spot and forward foreign currency transactions (including non-deliverable forwards ("NDFs") and forward rate agreements. The Fund may engage in such transactions in both U.S. and non-U.S. markets.

[26] Investment company securities include shares of other investment companies, including money market funds for which the Adviser and/or its affiliates serve as investment adviser or administrator. The Adviser will waive certain fees when investing in funds for which it serves as investment adviser, to the extent required by law or contract.

[27] Short-term funding agreements are agreements issued by banks and highly rated U.S. insurance companies such as Guaranteed Investment Contracts (GICs) and Bank Investment Contracts (BICs).

[28] Depositary Receipts are receipts, typically issued by a bank or trust company, which evidence ownership of underlying securities issued by a foreign corporation. For ADRs, the depository is typically a U.S. financial institution and the underlying securities are issued by a foreign issuer. For other Depositary Receipts, the depository may be a foreign or a U.S. entity, and the underlying securities may have a foreign or a U.S. issuer. Depositary Receipts will not necessarily be denominated in the same currency as their underlying securities. Generally, ADRs, in registered form, are designed for use in the U.S. securities market, and EDRs, in bearer form, are designated for use in European securities markets. GDRs are tradable both in the United States and in

The Fund may invest in convertible securities traded on an exchange or OTC that are not described in the Principal Holdings section above. Convertible securities are securities that may be converted or exchanged (by the holder or by the issuer) into shares of the underlying common stock (or cash or securities of equivalent value) at a stated exchange ratio. Convertible securities include contingent convertible securities.[29]

The Fund may invest in loan assignments and participations, which are assignments of, or participations in, all or a portion of loans to corporations or to governments, including governments in less developed countries. The Fund may also invest in commitments to purchase loan assignments.

The Fund may invest in exchange-traded master limited partnerships ("MLPs").

Investment Restrictions

The Fund may hold up to an aggregate amount of 15% of its Assets in illiquid assets (calculated at the time of investment), including Restricted Securities deemed illiquid by the Adviser[30] under the 1940 Act.[31] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, Assets, or other circumstances, more than 15% of the Fund's Assets are held in illiquid assets. A security is considered illiquid if it cannot be "sold or disposed of in the ordinary course of business within 7 days at approximately the value" at which it is being carried by the Fund.

The Fund intends to qualify each year as a regulated investment company (a "RIC") under Subchapter M of the Internal Revenue Code of 1986, as amended.[32] The Fund will invest its assets, and otherwise conduct its operations, in a manner that is intended to satisfy the qualifying income, diversification, and distribution requirements necessary to establish and maintain RIC qualification under Subchapter M.

The Fund does not have an investment objective seeking to return two times or three times the Fund's benchmark.

Net Asset Value

According to the Registration Statement, the NAV of the Fund's Shares generally will be calculated once daily Monday through Friday as of the close of regular trading on the Exchange, generally 4:00 p.m. Eastern Time (the "NAV Calculation Time") on each day that the Exchange is open for trading, based on prices at the NAV Calculation Time. NAV per Share is calculated by dividing the Fund's Assets by the number of Fund Shares outstanding. The Fund's Assets are valued primarily on the basis of market quotations. Expenses and fees, including the management fees, will be accrued daily and taken into account for purposes of determining NAV.

Convertible bonds, ARMs, ABS, bank obligations, corporate debt securities, inflation-linked debt securities, inverse floating rate instruments, mortgage dollar rolls, municipal securities, obligations of supranational agencies, private placements, restricted securities, and other unregistered securities, securities issued in connection with reorganizations and corporate restructurings, short-term funding agreements, sovereign obligations, stripped mortgage-backed securities, structured investments, treasury receipts, trust preferreds, U.S. Government Agency Securities, U.S. Government obligations, zero-coupon, pay-in-kind, and deferred payment securities, commercial paper, auction rate securities, when-issued securities, delayed delivery securities, and forward commitments, loan assignments and participations, and Brady Bonds will be valued at prices supplied by approved pricing services which is generally based on bid-side quotations. Non-ARM mortgages will be valued based on prices received from pricing vendor who provides bid prices. CDS will be valued at market quotations supplied by approved pricing services.

Common stocks and other exchange-traded equity securities (including shares of preferred securities, convertible securities, MLPs, commodity-related pooled investment vehicles, and ETFs) generally will be valued at the last sale price or official closing price on the primary exchange. Warrants and rights are generally valued at their intrinsic value. Custodial receipts are valued at their intrinsic value based on the terms of the receipts. Foreign equities and exchange-listed Depositary Receipts will be valued at the last sale price or official market closing price on the primary exchange and is subject to adjustment (fair value) each day by applying a fair value factor provided by approved pricing services. U.S. equity securities traded OTC, OTC-traded preferred securities, and OTC-traded convertible securities will be valued based on price quotations obtained from a broker-dealer who makes markets in such securities or other equivalent indications of value provided by a third-party pricing service. Securities of non-exchange traded investment companies will be valued at NAV.

Listed futures will generally be valued at the settlement price determined by the applicable exchange. Exchange-traded options on U.S. equity exchanges are generally valued at the composite mean price, using the National Best Bid and Offer quotes. Other exchange traded options are valued at the settlement price of the relevant exchange. Listed swaps will be valued on the basis of quotations or equivalent indication of value supplied by a third-party pricing service or broker-dealer who makes markets in such instruments. Non-exchange traded derivatives, including OTC-traded options and swaps are priced utilizing market quotations provided by approved pricing services. Foreign currency transactions will be valued based on foreign exchange rates obtained from an approved pricing service, using spot and forward rates

---

Europe and are designed for use throughout the world. The Fund will not invest in unsponsored ADRs. All exchange-traded equity securities in which the Fund may invest will trade on markets that are members of the Intermarket Surveillance Group ("ISG") or that have entered into a comprehensive surveillance agreement with the Exchange.

[29] A contingent convertible security is a hybrid debt security typically issued by a non-U.S. bank that may be convertible into equity or may be written down if a pre-specified trigger event such as a decline in capital ratio below a prescribed threshold occurs.

[30] In reaching liquidity decisions, the Adviser may consider factors including: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; the nature of the security and the nature of the marketplace in which it trades (*e.g.*, the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

[31] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding "Restricted Securities"); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[32] 26 U.S.C. 851.

available at the time net asset values of the fund is calculated.

Creation and Redemption of Shares

The NAV of Shares of the Fund will be determined once each business day, normally 4:00 p.m. Eastern time. The Fund currently anticipates that a Creation Unit will consist of 100,000 Shares, though this number may change from time to time, including prior to the listing of the Fund. The exact number of Shares that will comprise a Creation Unit will be disclosed in the Registration Statement of the Fund. The Trust will issue and sell Shares of the Fund only in Creation Units on a continuous basis, without a sales load (but subject to transaction fees), at their NAV per Share next determined after receipt of an order, on any business day, in proper form. Creation and redemption will typically occur in cash, however, the Trust retains discretion to conduct such transactions on an in-kind basis or a combination of cash and in-kind, as further described below.

The consideration for purchase of a Creation Unit of the Fund generally will consist of either (i) the in-kind deposit of a designated portfolio of securities (the "Deposit Securities") per each Creation Unit and the Cash Component (defined below), computed as described below, or (ii) the cash value of the Deposit Securities ("Deposit Cash") and the "Cash Component," computed as described below. When accepting purchases of Creation Units for cash, the Fund may incur additional costs associated with the acquisition of Deposit Securities that would otherwise be provided by an in-kind purchaser. Together, the Deposit Securities or Deposit Cash, as applicable, and the Cash Component constitute the "Fund Deposit," which represents the minimum initial and subsequent investment amount for a Creation Unit of the Fund. The "Cash Component" is an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the market value of the Deposit Securities or Deposit Cash, as applicable. If the Cash Component is a positive number (*i.e.*, the NAV per Creation Unit exceeds the market value of the Deposit Securities or Deposit Cash, as applicable), the Cash Component shall be such positive amount. If the Cash Component is a negative number (*i.e.*, the NAV per Creation Unit is less than the market value of the Deposit Securities or Deposit Cash, as applicable), the Cash Component will be such negative amount and the creator will be entitled to receive cash in an amount equal to the Cash Component. The Cash Component serves the function of compensating for any differences between the NAV per Creation Unit and the market value of the Deposit Securities or Deposit Cash, as applicable.

The Custodian, through the National Securities Clearing Corporation ("NSCC"), will make available on each business day, prior to the opening of business on the Exchange, the list of the names and the required amount of each Deposit Security or the required amount of Deposit Cash, as applicable, to be included in the current Fund Deposit (based on information at the end of the previous business day) for the Fund. Such Fund Deposit is subject to any applicable adjustments as described in the Registration Statement, in order to effect purchases of Creation Units of the Fund until such time as the next-announced composition of the Deposit Securities or the required amount of Deposit Cash, as applicable, is made available.

Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Fund through the Transfer Agent and only on a business day.

With respect to the Fund, the Custodian, through the NSCC, will make available immediately prior to the opening of business on the Exchange (9:30 a.m. Eastern time) on each business day, the list of the names and share quantities of the Fund's portfolio securities that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form on that day ("Fund Securities"). Fund Securities received on redemption may not be identical to Deposit Securities.

Redemption proceeds for a Creation Unit will be paid either in-kind or in cash or a combination thereof, as determined by the Trust. With respect to in-kind redemptions of the Fund, redemption proceeds for a Creation Unit will consist of Fund Securities as announced by the Custodian on the business day of the request for redemption received in proper form plus cash in an amount equal to the difference between the NAV of the Shares being redeemed, as next determined after a receipt of a request in proper form, and the value of the Fund Securities (the "Cash Redemption Amount"), less a fixed redemption transaction fee and any applicable additional variable charge as set forth in the Registration Statement. In the event that the Fund Securities have a value greater than the NAV of the Shares, a compensating cash payment equal to the differential will be required to be made by or through an authorized participant by the redeeming shareholder. Notwithstanding the foregoing, at the Trust's discretion, an authorized participant may receive the corresponding cash value of the securities in lieu of the in-kind securities value representing one or more Fund Securities.[33]

The creation/redemption order cut-off time for the Fund is expected to be 4:00 p.m. Eastern time. Creation/redemption order cut-off times may be earlier on any day that the Securities Industry and Financial Markets Association ("SIFMA") (or applicable exchange or market on which the Fund's investments are traded) announces an early closing time. On days when the Exchange closes earlier than normal, the Fund may require orders for Creation Units to be placed earlier in the day.

Availability of Information

The Fund's Web site, which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Web site will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's reported NAV, mid-point of the bid/ask spread at the time of calculation of such NAV (the "Bid/Ask Price"),[34] daily trading volume, and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Daily trading volume information for the Fund will also be available through subscription services such as Bloomberg, Thomson Reuters, and International Data Corporation, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public Web sites. On each business day, before commencement of trading in Shares during Regular Trading Hours[35] on the

---

[33] The Adviser represents that, to the extent that the Trust permits or requires a "cash in lieu" amount, such transactions will be effected in the same or equitable manner for all Authorized Participants.

[34] The Bid/Ask Price of the Fund will be determined using the midpoint of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[35] Regular Trading Hours are 9:30 a.m. to 4:00 p.m. Eastern Time.

Exchange, the Fund will disclose on its Web site the identities and quantities of the portfolio of securities and other assets (the "Disclosed Portfolio") held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.[36] The Disclosed Portfolio will include, as applicable: The ticker symbol; CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, commodity, index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund's portfolio. The Web site and information will be publicly available at no charge.

In addition, for the Fund, an estimated value, defined in BZX Rule 14.11(i)(3)(C) as the "Intraday Indicative Value," that reflects an estimated intraday value of the Fund's portfolio, will be disseminated. Moreover, the Intraday Indicative Value will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Trading Hours.[37] In addition, the quotations of certain of the Fund's holdings may not be updated during U.S. trading hours if such holdings do not trade in the United States or if updated prices cannot be ascertained.

The dissemination of the Intraday Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and provide a close estimate of that value throughout the trading day.

Intraday, closing, and settlement prices of common stocks and other exchange-listed instruments (including futures, options, Depositary Receipts, preferred securities, convertible securities, warrants, rights, MLPs, commodity-related pooled investment vehicles, and ETFs) will be readily available from the exchanges trading such securities as well as automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. In addition, price information for U.S. exchange-traded options will be available from the Options Price Reporting Authority. Quotation information from brokers and dealers or pricing services will be available for Fixed Income Securities and U.S. government obligations. Quotation and price information for convertible bonds, ARMs, ABS, bank obligations, custodial receipts, corporate debt securities, inflation-linked debt securities, inverse floating rate instruments, mortgage dollar rolls, municipal securities, obligations of supranational agencies, private placements, restricted securities, and other unregistered securities, securities issued in connection with reorganizations and corporate restructurings, short-term funding agreements, sovereign obligations, stripped mortgage-backed securities, structured investments, treasury receipts, trust preferreds, U.S. Government Agency Securities, U.S. Government obligations, zero-coupon, pay-in-kind, and deferred payment securities, commercial paper, auction rate securities, when-issued securities, delayed delivery securities, and forward commitments, loan assignments and participations, Brady Bonds, mortgages, common stock warrants and rights, CDS, and foreign currency transactions will be available via major market data vendors or broker dealers that make markets in such instruments.

Information regarding market price and volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available on the facilities of the CTA.

Initial and Continued Listing

The Shares will be subject to BZX Rule 14.11(i), which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[38] A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 14.11(i)(2)(C), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange traded investment companies, U.S. equity securities, foreign equity securities, futures, and options via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[39] In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine ("TRACE"). The Exchange can also access municipal bond trading activity for surveillance purposes in connection with trading in the Shares through the Electronic Municipal Market Access ("EMMA")[40] of the Municipal Securities Rulemaking Board ("MSRB"). The Exchange prohibits the distribution of material non-public information by its employees.

---

[36] Under accounting procedures to be followed by the Fund, trades made on the prior business day ("T") will be booked and reflected in NAV on the current business day ("T + 1"). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[37] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Intraday Indicative Values published via the Consolidated Tape Association ("CTA") or other data feeds.

[38] *See* 17 CFR 240.10A–3.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (4) the risks involved in trading the Shares during the Pre-Opening[41] and After Hours Trading Sessions[42] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV Calculation Time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's Web site. In addition, the Information Circular will reference that the Trust is subject to various fees and expenses described in the Fund's Registration Statement.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[43] in general and Section 6(b)(5) of the Act[44] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in BZX Rule 14.11(i). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. If the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser to the investment company shall erect a "fire wall" between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. The Adviser is not a registered broker-dealer, but is affiliated with a broker-dealer and has implemented a "fire wall" with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio. In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio. The Exchange may obtain information regarding trading in the Shares and the underlying Depositary Receipts, exchange traded shares of investment companies, U.S. equity securities, futures, and exchange listed options via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[45] In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's TRACE.

The Fund's investments will be consistent with the Fund's investment objective and the Fund does not have an investment objective seeking to return two times or three times the Fund's benchmark, as stated above.

In addition to the holdings in Bonds and Non-Bonds described above as part of the Fund's principal investment strategy, the Fund may also, to a limited extent (under normal circumstances, less than 20% of the Fund's Assets) and as further described above, engage in transactions in the following:

---

[39] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also notes that all exchange-traded instruments, including ETFs, commodity-related pooled investment vehicles, futures, and options will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[40] Information available from EMMA includes next-day information regarding municipal securities transactions and par amounts traded.

[41] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[42] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[43] 15 U.S.C. 78f.

[44] 15 U.S.C. 78f(b)(5).

[45] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also notes that all of the ETFs, commodity-related pooled investment vehicles, futures, and options will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Auction rate securities, Brady Bonds, commodity-related pooled investment vehicles, commodity-linked derivatives, U.S. equity securities, exchange-traded common stocks of foreign corporations, exchange-traded warrants of foreign corporations, exchange-traded rights in foreign corporations, ADRs, GDRs, EDRS, convertible securities, and MLPs.

The Fund may hold up to an aggregate amount of 15% of its Assets in illiquid assets (calculated at the time of investment), including Restricted Securities deemed illiquid by the Adviser[46] under the 1940 Act.[47] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, Assets, or other circumstances, more than 15% of the Fund's Assets are held in illiquid assets. A security is considered illiquid if it cannot be "sold or disposed of in the ordinary course of business within 7 days at approximately the value" at which it is being carried by the fund.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value will be disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours. On each business day, before commencement of trading in Shares during Regular Trading Hours, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Pricing information will be available on the Fund's Web site including: (1) The prior business day's reported NAV, the Bid/Ask Price of the Fund, and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Additionally, information regarding market price and trading of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available on the facilities of the CTA. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted under the conditions specified in BZX Rule 11.18. Trading may also be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Finally, trading in the Shares will be subject to BZX Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted. In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's TRACE. As noted above, investors will also have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

Intraday, closing, and settlement prices of common stocks and other exchange-listed instruments (including futures, options, Depositary Receipts, preferred securities, convertible securities, warrants, rights, MLPs, commodity-related pooled investment vehicles, and ETFs) will be readily available from the exchanges trading such securities as well as automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. In addition, price information for U.S. exchange-traded options will be available from the Options Price Reporting Authority. Quotation information from brokers and dealers or pricing services will be available for Fixed Income Securities and U.S. government obligations. Quotation and price information for convertible bonds, ARMs, ABS, bank obligations, custodial receipts, corporate debt securities, inflation-linked debt securities, inverse floating rate instruments, mortgage dollar rolls, municipal securities, obligations of supranational agencies, private placements, restricted securities, and other unregistered securities, securities issued in connection with reorganizations and corporate restructurings, short-term funding agreements, sovereign obligations, stripped mortgage-backed securities, structured investments, treasury receipts, trust preferreds, U.S. Government Agency Securities, U.S. Government obligations, zero-coupon, pay-in-kind, and deferred payment securities, commercial paper, auction rate securities, when-issued securities, delayed delivery securities, and forward commitments, loan assignments and participations, Brady Bonds, mortgages, common stock warrants and rights, CDS, and foreign currency transactions will be available via major market data vendors or broker dealers that make markets in such instruments.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

---

[46] In reaching liquidity decisions, the Adviser may consider factors including: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; the nature of the security and the nature of the marketplace in which it trades (*e.g.*, the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

[47] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also*, Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding "Restricted Securities"); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBZX–2016–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–35 and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[48]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16615 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[48] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78262; File No. SR–BatsBZX–2016–30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, To List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust

July 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on June 30, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade Winklevoss Bitcoin Shares (the "Shares") issued by the Winklevoss Bitcoin Trust (the "Trust") under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4),[4] which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.[5] The Shares will be offered by the Trust, which was established as a Delaware statutory trust on December 30, 2014. The Trust will not be registered as an investment company under the Investment Company Act of 1940[6] and is not required to register under such act. The Trust will not be a commodity pool for purposes of the Commodity Exchange Act ("CEA").[7] The Shares of the Trust will be registered with the Commission by means of the Trust's registration statement on Form S–1 (the "Registration Statement") under the Securities Act of 1933 (the "Securities Act"). The most recent amendment to the Registration Statement was filed on June 29, 2016 and the Registration Statement will be effective as of the date of any offer and sale pursuant to the Registration Statement.[8]

---

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[5] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

Service providers of the Trust

Digital Asset Services, LLC, formerly Math-Based Asset Services, LLC, will be the sponsor of the Trust (the "Sponsor").[9] The Trust's administrator (the "Administrator")[10] and trust agency service provider (the "Trust Agency Service Provider") will be the same entity.[11] Gemini Trust Company, LLC will be the custodian of the Trust (the "Custodian").[12] The Custodian is a New York State-chartered limited liability trust company that operates under the direct supervision and regulatory authority of the NYSDFS. The Custodian is a fiduciary and must meet the capitalization, compliance, anti-money laundering, consumer protection and cyber security requirements as set forth by the NYSDFS. The Custodian will hold the bitcoin deposited with the Custodian on behalf of the Trust in a segregated custody account (the "Trust Custody Account") in accordance with the Trust Custody Agreement. The Custodian will use its proprietary and patent-pending offline (*i.e.,* air-gapped) Cold Storage System to store the Trust's bitcoin, as further described herein. Delaware Trust Company acts as the trustee of the Trust (the "Trustee").[13]

The Trust will only hold bitcoin, which is a digital commodity[14] that is not issued by any government, bank or central organization. Bitcoin is a digital asset ("Digital Asset") based on the decentralized, open source protocol of the peer-to-peer Bitcoin computer network (the "Bitcoin Network" or "Bitcoin")[15] that hosts the decentralized public transaction ledger, known as the "Blockchain," on which all bitcoin is recorded. The Bitcoin Network software source code includes the protocols that govern the creation of bitcoin and the cryptographic system that secures and verifies Bitcoin transactions.

The Trust is expected to issue and redeem Shares from time to time only in one or more whole Baskets. Certain Authorized Participants are the only persons that may place orders to create or redeem Baskets. Authorized Participants or their affiliated market makers are expected to have the facility to participate directly on one or more Bitcoin Exchanges (as defined below).

The investment objective of the Trust is for the Shares to track the price of bitcoin, as measured by the spot price at 4:00 p.m. Eastern time on the Gemini exchange ("Gemini Exchange") (the "Gemini Exchange Spot Price"), each day the Exchange is open for trading (each a "Business Day"), less the Trust's liabilities (which include accrued but unpaid fees and expenses). The Gemini Exchange is a Digital Asset exchange owned and operated by the Custodian and is an affiliate of the Sponsor. The Gemini Exchange does not receive any compensation from the Trust or the Sponsor for providing the Gemini

---

[6] 15 U.S.C. 80a–1.

[7] 17 U.S.C. 1.

[8] *See* Registration Statement on Form S–1, dated June 29, 2016 (File No. 333–189752). The descriptions of the Trust and the Shares contained herein are based, in part, on information in the Registration Statement.

[9] The Sponsor is a Delaware limited liability company formed on May 9, 2013, and is wholly-owned by Winklevoss Capital Management LLC. Under the Delaware Limited Liability Company Act and the governing documents of the Sponsor, Winklevoss Capital Management LLC, the sole member of the Sponsor, is not responsible for the debts, obligations and liabilities of the Sponsor solely by reason of being the sole member of the Sponsor. The Sponsor will be the exclusive licensee, within the field of use of operation of an exchange-traded product ("ETP"), of certain patent-pending intellectual property regarding the operation of the Trust. Winklevoss IP LLC, an affiliate of the Sponsor, is the owner of and is licensing to the Sponsor such intellectual property for use by the Trust and the Custodian and other service providers in the operation of the Trust. The Sponsor arranged for the creation of the Trust and will arrange for the registration of the Shares for their public offering in the United States and their listing on the Exchange.

[10] The Administrator is generally responsible for the day-to-day administration of the Trust under the trust servicing agreement ("Trust Servicing Agreement") and in accordance with the provisions of the trust agreement ("Trust Agreement"). This includes (1) assisting the Sponsor in receiving and processing orders from authorized participants ("Authorized Participants") to create and redeem blocks of 50,000 Shares (a block of 50,000 Shares is called a "Basket") and coordinating the processing of such orders with the Trust Agency Service Provider (which, in this case is, or is affiliated with, the Administrator) and The Depository Trust Company ("DTC"), (2) calculating the net asset value per Share ("NAV"), (3) instructing the Custodian to transfer the Trust's bitcoin as needed to pay the remuneration due to the Sponsor ("Sponsor's Fee") in bitcoin (such Bitcoin transfers are expected to occur approximately monthly in the ordinary course), (4) instructing the Custodian to transfer the Trust's bitcoin as needed to pay any extraordinary Trust expenses that are not assumed by the Sponsor and (5) selling or directing the sale of the Trust's remaining bitcoin in the event of termination of the Trust and distributing the cash proceeds to the owners of beneficial interests in the Shares ("Shareholders") of record.

[11] The Trust Agency Service Provider is authorized by the Sponsor under the Trust Agreement to serve as the transfer agent in accordance with the provisions of the Trust Agency Service Provider Agreement. The Trust Agency Service Provider, among other things, provides transfer agent services with respect to the creation and redemption of Baskets by Authorized Participants. The Trust Agency Service Provider is, or is affiliated with, the Administrator.

[12] The Custodian is an affiliate of the Sponsor and a New York State-chartered limited liability trust company that operates under the direct supervision and regulatory authority of the New York State Department of Financial Services ("NYSDFS"). Although the Trust's bitcoin is not stored in a physical sense, all transactions involving the Trust's bitcoin are recorded on the Bitcoin Network's Blockchain and associated with a public Bitcoin address. The Trust's public Bitcoin addresses are established by the Custodian using its proprietary hardware and software security technology ("Cold Storage System"), which holds the Trust's bitcoin and permits the Trust to move its bitcoin. Access and control of those Bitcoin addresses, and the bitcoin associated with them, is restricted through the public-private key pair relating to each Bitcoin address. The Custodian is responsible for the safekeeping of the Trust's private keys used to access and transfer the Trust's bitcoin. The Custodian also facilitates the transfer of bitcoin in accordance with the Administrator's instructions pursuant to the terms of the Trust Servicing Agreement. Pursuant to the terms of the Trust Agreement and the trust custody agreement ("Trust Custody Agreement"), the Custodian will store all of the Trust's bitcoin on a segregated basis in its unique Bitcoin addresses with balances that can be directly verified on the Blockchain. It will provide the Trust's public Bitcoin addresses to the Administrator. Pursuant to the provisions of the Trust Custody Agreement, the Custodian will use the Cold Storage System to manage and safeguard a system utilizing numerous Bitcoin addresses that are kept offline either (i) in computers that are not directly connected to or accessible from the internet or (ii) through the storage of the public and private keys relating to such Bitcoin addresses only in "cold storage."

[13] The Trustee, a Delaware trust company, acts as the trustee of the Trust for the purpose of creating a Delaware statutory trust in accordance with the Delaware Statutory Trust Act ("DSTA"). The duties of the Trustee will be limited to (i) accepting legal process served on the Trust in the State of Delaware and (ii) the execution of any certificates required to be filed with the Delaware Secretary of State which the Delaware Trustee is required to execute under the DSTA. To the extent that, at law or in equity, the Trustee has duties (including fiduciary duties) and liabilities relating thereto to the Trust or the Shareholders, such duties and liabilities will be replaced by the duties and liabilities of the Trustee expressly set forth in the Trust Agreement.

[14] Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. 7 U.S.C. 1a(9). *See In re* Coinflip, Inc., No. 15–29 (CFTC Sept. 17, 2015), *available at: http://www.cftc.gov/ucm/groups/public/@lrenforcementactions/documents/legalpleading/enfcoinfliprorder09172015.pdf* ("Coinflip").

[15] By common convention, Bitcoin with a capital "B" typically refers to the Bitcoin Network as a whole, whereas bitcoin with a lowercase "b" refers to the Digital Asset of the Bitcoin Network, including the Trust's bitcoin. This naming convention is used throughout this document.

Exchange Spot Price. The Sponsor believes that, for many investors, the Shares will represent a cost-effective and convenient means of gaining investment exposure to bitcoin similar to a direct investment in bitcoin. The Shares represent units of fractional undivided beneficial interest in and ownership of the Trust and are expected to be traded under the ticker symbol "COIN" on the Exchange.

Overview of the Bitcoin Industry and Market

Bitcoin is a Digital Asset that is issued by, and transmitted through, the decentralized, open source protocol of the peer-to-peer Bitcoin Network. The Bitcoin Network hosts the decentralized public transaction ledger, known as the Blockchain, on which all bitcoin is recorded. No single entity owns or operates the Bitcoin Network, the infrastructure of which is collectively maintained by a decentralized user base. Bitcoin can be used to pay for goods and services or can be converted to fiat currencies, such as the U.S. Dollar, at rates determined on bitcoin exchanges (each a "Bitcoin Exchange") [16] or in individual end-user-to-end-user transactions under a barter system. See "Uses of Bitcoin—Bitcoin Exchange Market," below.

Bitcoin is "stored" or reflected on the Blockchain, which is a digital file stored in a decentralized manner on the computers of each Bitcoin Network user. The Bitcoin Network software source code includes the protocols that govern the creation of bitcoin and the cryptographic system that secures and verifies Bitcoin transactions. The Blockchain is a canonical record of every bitcoin, every Bitcoin transaction (including the creation or "mining" of new bitcoin) and every Bitcoin address associated with a quantity of bitcoin. The Bitcoin Network and Bitcoin Network software programs can interpret the Blockchain to determine the exact bitcoin balance, if any, of any public Bitcoin address listed in the Blockchain as having taken part in a transaction on the Bitcoin Network. The Bitcoin Network utilizes the Blockchain to evidence the existence of bitcoin in any public Bitcoin address. A Bitcoin private key controls the transfer or "spending" of bitcoin from its associated public Bitcoin address. A Bitcoin "wallet" is a collection of private keys and their associated public Bitcoin addresses.

The Blockchain is comprised of a digital file, downloaded and stored, in whole or in part, on all Bitcoin Network users' software programs. The file includes all blocks that have been solved by miners and is updated to include new blocks as they are solved. See "Bitcoin Mining & Creation of New Bitcoin." As each newly solved block refers back to and "connects" with the immediately prior solved block, the addition of a new block adds to the Blockchain in a manner similar to a new link being added to a chain. Each new block records outstanding Bitcoin transactions, and outstanding transactions are settled and validated through such recording. The Blockchain represents a complete, transparent and unbroken history of all transactions of the Bitcoin Network. Each Bitcoin transaction is broadcast to the Bitcoin Network and recorded in the Blockchain.

The Bitcoin Network is decentralized and does not rely on either governmental authorities or financial institutions to create, transmit or determine the value of bitcoin. Rather, bitcoin is created and allocated by the Bitcoin Network protocol through a "mining" process subject to a strict, well-known issuance schedule. The value of bitcoin is determined by the supply of and demand for bitcoin in the "Bitcoin Exchange Market" [17] (and in private end-user-to-end-user transactions), as well as the number of merchants that accept them. As Bitcoin transactions can be broadcast to the Bitcoin Network by any user's Bitcoin Network software and bitcoin can be transferred without the involvement of intermediaries or third parties, there are currently little or no transaction fees in direct peer-to-peer transactions on the Bitcoin Network. Third party service providers such as Bitcoin Exchanges and third-party Bitcoin payment processing services may charge fees for processing transactions and for converting, or facilitating the conversion of, bitcoin to or from fiat currency.

The Bitcoin Network was initially contemplated in a white paper that also described bitcoin and the operating software to govern the Bitcoin Network. The white paper was purportedly authored by Satoshi Nakamoto; however, no individual with that name has been reliably identified as Bitcoin's creator, and the general consensus is that the name is a pseudonym for the actual inventor or inventors. The first bitcoin was created in 2009 after Nakamoto released the Bitcoin Network source code (the software and protocol that created and launched the Bitcoin Network). Since its introduction, the Bitcoin Network has been under active development by a group of contributors currently headed by Wladimir J. van der Laan who was appointed project maintainer in April 2014 by Gavin Andresen (who was previously appointed maintainer by Satoshi Nakamoto in 2010). As an open source project, Bitcoin is not represented by an official organization or authority.

Overview of the Bitcoin Network's Operations

In order to own, transfer or use bitcoin, a person generally must have Internet access to connect to the Bitcoin Network. Bitcoin transactions may be made directly between end-users without the need for a third-party intermediary, although there are entities that provide third-party intermediary services. To prevent the possibility of double-spending bitcoin, a user must notify the Bitcoin Network of the transaction by broadcasting the transaction data to its network peers. The Bitcoin Network provides confirmation against double-spending by memorializing every transaction in the Blockchain, which is publicly accessible and transparent. This memorialization and verification against double-spending is accomplished through the Bitcoin Network mining process, which adds "blocks" of data, including recent transaction information, to the Blockchain. See "Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System," below.

Brief Description of Bitcoin Transfers

Prior to engaging in Bitcoin transactions, a user generally must first install on its computer or mobile device a Bitcoin Network software program that will allow the user to generate a private and public key pair associated with a Bitcoin address (analogous to a Bitcoin account). The Bitcoin Network software program and the Bitcoin address also enable the user to connect to the Bitcoin Network and engage in the transfer of bitcoin with other users. The computer of a user that downloads a version of the Bitcoin Network software program will become a "node" on the Bitcoin Network that assists in validating and relaying transactions from other users. *See* "Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System," below. Alternatively, a user may retain a third party to create a Bitcoin address, or collection of Bitcoin addresses known as a digital wallet to be used for the same purpose. There is no limit on the number of Bitcoin addresses a user can have, and each such Bitcoin address consists of a "public key" and a "private key," which are mathematically related. *See* "Cryptographic Security Used in the Bitcoin Network—Public and Private Keys," below.

---

[16] The Gemini Exchange is a United States-based Bitcoin Exchange that began trading on October 8, 2015. It is currently operational in 31 states and Washington, DC and allows trading between Bitcoin, U.S. Dollars, and other Digital Assets.

[17] For purposes of this filing, the term Bitcoin Exchange Market means the global Bitcoin Exchange Market for the trading of bitcoin, which consists of transactions on various electronic Bitcoin Exchanges.

In a Bitcoin transaction, the bitcoin recipient must provide its public Bitcoin address, which serves as a routing number for the recipient on the Blockchain, to the party initiating the transfer. This activity is analogous to a recipient providing a routing address in wire instructions to the payor so that cash may be wired to the recipient's account. The recipient, however, does not make public or provide to the sender its related private key. The payor, or "spending" party, does reveal its public key in signing and verifying its spending transaction to the Blockchain.

Neither the recipient nor the sender reveal their public Bitcoin addresses' private key in a transaction, because the private key authorizes access to, and transfer of, the funds in that Bitcoin address to other users. Therefore, if a user loses his private key, the user permanently loses access to the bitcoin contained in the associated Bitcoin address. Likewise, bitcoin is irretrievably lost if the private key associated with them is deleted and no backup has been made. When sending bitcoin, a user's Bitcoin Network software program must "sign" the transaction with the associated private key. The resulting digitally signed transaction is sent by the user's Bitcoin Network software program to the Bitcoin Network to allow transaction confirmation. The digital signature serves as validation that the transaction has been authorized by the holder of the Bitcoin addresses' private key. This signature process is typically automated by software that has access to the public and private keys.

Summary of a Bitcoin Transaction

In a Bitcoin transaction between two parties, the following circumstances must be in place: (i) The party seeking to send bitcoin must have a public Bitcoin address and the Bitcoin Network must recognize that public Bitcoin address as having sufficient bitcoin for the spending transaction; (ii) the receiving party must have a public Bitcoin address; and (iii) the spending party must have Internet access with which to send its spending transaction.

Next, the receiving party must provide the spending party with its public Bitcoin address, an identifying series of twenty-seven (27) to thirty-four (34) alphanumeric characters that represents the routing number on the Bitcoin Network and allow the Blockchain to record the sending of bitcoin to that public Bitcoin address. The receiving party can provide this address to the spending party in alphanumeric format or an encoded format such as a Quick Response Code (commonly known as a QR Code), which may be scanned by a smartphone or other device to quickly transmit the information.

After the provision of a recipient's public Bitcoin address, the spending party must enter the address into its Bitcoin Network software program along with the number of bitcoin to be sent. The number of bitcoin to be sent will typically be agreed upon between the two parties based on a set number of bitcoin or an agreed upon conversion of the value of fiat currency to bitcoin. Most Bitcoin Network software programs also allow, and often suggest, the payment of a transaction fee (also known as a miner's fee). Transaction fees are not required to be included by many Bitcoin Network software programs, but, when they are included, they are paid by the spending party on top of the specified amount of bitcoin being sent in the transaction. Transaction fees, if any, are typically a fractional number of bitcoin (*e.g.,* 0.005 or 0.0005 bitcoin) and are automatically transferred by the Bitcoin Network to the Bitcoin Network miner that solves and adds the block recording the spending transaction on the Blockchain.

After the entry of the Bitcoin address, the number of bitcoin to be sent and the transaction fees, if any, to be paid, the spending party will transmit the spending transaction. The transmission of the spending transaction results in the creation of a data packet by the spending party's Bitcoin Network software program, which data packet includes data showing (i) the destination public Bitcoin address, (ii) the number of bitcoin being sent, (iii) the transaction fees, if any, and (iv) the spending party's digital signature, verifying the authenticity of the transaction. The data packet also includes references called "inputs" and "outputs," which are used by the Blockchain to identify the source of the bitcoin being spent and record the flow of bitcoin from one transaction to the next transaction in which the bitcoin is spent. The digital signature exposes the spending party's public Bitcoin address and public key to the Bitcoin Network, though, for the receiving party, only its public Bitcoin address is revealed. The spending party's Bitcoin Network software will transmit the data packet onto the decentralized Bitcoin Network, resulting in the propagation of the information among the software programs of Bitcoin users across the Bitcoin Network for eventual inclusion in the Blockchain. Typically, the data will spread to a vast majority of Bitcoin Network miners within the course of less than a minute.

As discussed in greater detail below in "Bitcoin Mining & Creation of New Bitcoin," Bitcoin Network miners record transactions when they solve for and add blocks of information to the Blockchain. When a miner solves for a block, it creates that block, which includes data relating to (i) the solution to the block, (ii) a reference to the prior block in the Blockchain to which the new block is being added and (iii) transactions that have occurred but have not yet been added to the Blockchain. The miner becomes aware of outstanding, unrecorded transactions through the data packet transmission and propagation discussed above. Typically, Bitcoin transactions will be recorded in the next chronological block if the spending party has an Internet connection and at least one (1) minute has passed between the transaction's data packet transmission and the solution of the next block. If a transaction is not recorded in the next chronological block, it is usually recorded in the next block thereafter.

Upon the addition of a block included in the Blockchain, the Bitcoin Network software program of both the spending party and the receiving party will show confirmation of the transaction on the Blockchain and reflect an adjustment to the bitcoin balance in each party's public Bitcoin address, completing the bitcoin transaction. Typically, Bitcoin Network software programs will automatically check for and display additional confirmations of six or more blocks in the Blockchain. See "Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System."

Cryptographic Security Used in the Bitcoin Network

Public and Private Keys

The Bitcoin Network uses sophisticated cryptography to maintain the integrity of the Blockchain ledger. Transactions are digitally signed by their senders. Before adding a transaction to a block, miners will verify both that the sender has not already spent the bitcoin being sent and that the digital signature information in the transaction is valid. Besides the requirement of containing only valid transactions (as described in the preceding sentence), blocks are validated by means of properties of their cryptographic hashes. By extension, blocks in the Blockchain can be validated by verifying that each block contains the cryptographic hash of the prior block. The cryptographic algorithms and cryptographic parameters, including key sizes, used by the Bitcoin Network provide adequate security for the foreseeable future.

Double-Spending and the Bitcoin Network Confirmation System

To ensure the integrity of Bitcoin transactions from the recipient's side (*i.e.,* to prevent double-spending by a spending party), every Bitcoin transaction is broadcast to the Bitcoin Network and recorded in the Blockchain through the "mining" process, which time-stamps the transaction and memorializes the change in the ownership of bitcoin transferred. See "Bitcoin Mining & Creation of New Bitcoin," below. Adding a block to the Blockchain requires Bitcoin Network miners to exert significant computational effort. Requiring this "proof of work" prevents a malicious actor from either adding fraudulent blocks to generate bitcoin (*i.e.,* counterfeit bitcoin) or overwriting existing valid blocks to reverse prior transactions.

A Bitcoin transaction between two parties is recorded in the Blockchain in a block only if that block is accepted as valid by a majority of the nodes on the Bitcoin Network. Validation of a block is achieved by confirming the cryptographic hash value included in the block's solution and by the block's addition to the longest confirmed Blockchain on the Bitcoin Network. For a transaction, inclusion in a block on the Blockchain constitutes a "confirmation" of a Bitcoin transaction. As each block contains a reference to the immediately preceding block, additional blocks appended to and incorporated into the Blockchain constitute additional confirmations of the transactions in such prior blocks, and a transaction included in a block for the first time is confirmed once against double-spending. The layered confirmation process makes changing historical blocks (and reversing transactions) exponentially more difficult the further back one goes in the Blockchain. Bitcoin Exchanges and users can set their own threshold as to how many confirmations they require until funds from the transferor are considered valid.

To undo past transactions in a block recorded on the Blockchain, a malicious actor would have to exert tremendous hashrate in resolving each block in the Blockchain starting with and after the target block and broadcasting all such blocks to the Bitcoin Network. The Bitcoin Network is generally programmed to consider the longest Blockchain containing solved blocks to be the most accurate Blockchain. In order to undo multiple layers of confirmation and alter the Blockchain, a malicious actor must resolve all of the old blocks sought to be regenerated and be able to continuously add new blocks to the Blockchain at a speed that would have to outpace that of all of the other miners on the Bitcoin Network, who would be continuously solving for and adding new blocks to the Blockchain. Given the size and speed of the Bitcoin Network, it is generally agreed that the cost of amassing such computational power exceeds the profit to be obtained by double-spending or attempting to fabricate prior blocks.

If a malicious actor is able to amass ten (10) percent of the Bitcoin Network's aggregate hashrate, there is estimated to be a 0.1 percent chance that it would be able to overcome six (6) confirmations. Therefore, given the difficulty in amassing such hashrate, six (6) confirmations is an often-cited standard for the validity of transactions. The Trust has adopted a policy whereby a transaction will be deemed confirmed upon this industry standard of six (6) confirmations (the "Confirmation Protocol"). As one (1) block is added to the Blockchain approximately every six (6) to twelve (12) minutes, a Bitcoin transaction will be, on average, confirmed using the Confirmation Protocol beyond a reasonable doubt in approximately one (1) hour. Merchants selling high-value goods and services, as well as Bitcoin Exchanges and many experienced users, are believed to generally use the six (6) confirmations standard. This confirmation system, however, does not mean that merchants must always wait for multiple confirmations for transactions involving low-value goods and services. As discussed below, the value of a successful double-spending attack involving a low-value transaction may, and perhaps likely will, be significantly less than the cost involved in arranging and executing such double-spending attacks. Furthermore, merchants engaging in low-value transactions may then view the reward of quicker transaction settlements with limited or no Blockchain confirmation as greater than the related risk of not waiting for six (6) confirmations with respect to low-value transactions at points of sale. Conversely, for high-value transactions that are not time sensitive, additional settlement security can be provided by waiting for more than six (6) confirmations.

Bitcoin Mining & Creation of New Bitcoin

Mining Process

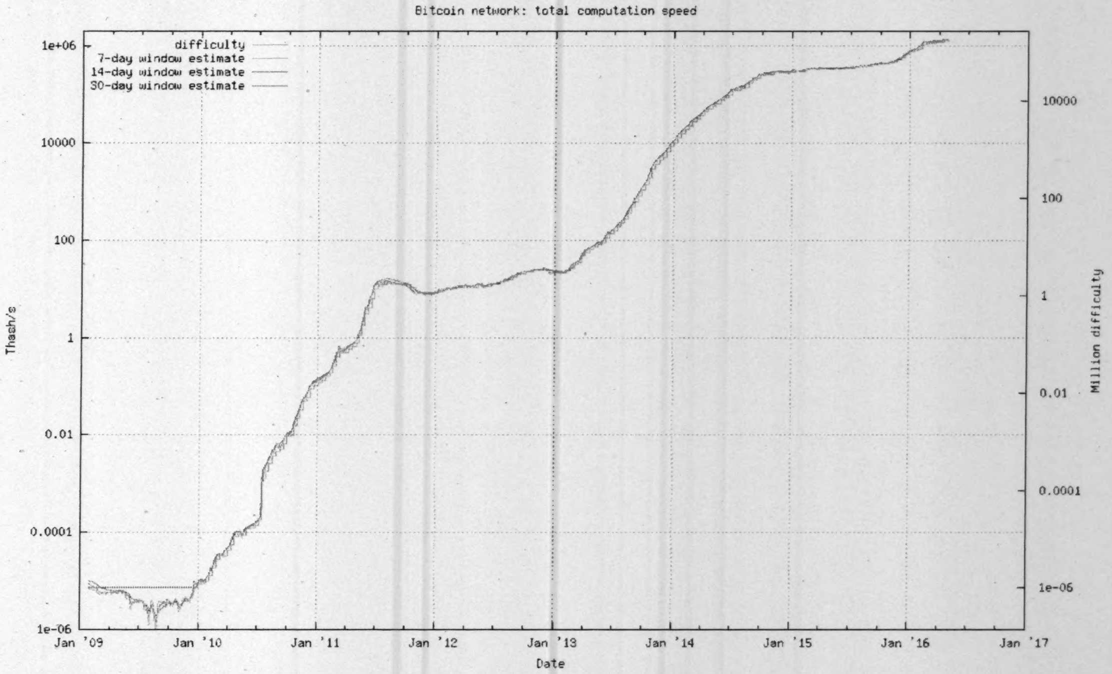
The process by which bitcoin is "mined" results in new blocks being added to the Blockchain and new bitcoin being issued to the miners. Bitcoin Network miners engage in a set of prescribed complex mathematical calculations in order to add a block to the Blockchain and thereby confirm Bitcoin transactions included in that block's data. Miners that are successful in adding a block to the Blockchain are automatically awarded a fixed number of bitcoin for their effort. This reward system is the method by which new bitcoin enter into circulation to the public and is accomplished in the added block through the notation of the new bitcoin creation and their allocation to the successful miner's public Bitcoin address. To begin mining, a user can download and run Bitcoin Network mining software, which, like regular Bitcoin Network software programs, turns the user's computer into a "node" on the Bitcoin Network that validates blocks. See "Overview of the Bitcoin Network's Operations," above.

All Bitcoin transactions are recorded in blocks added to the Blockchain. Each block contains (i) the details of some or all of the most recent transactions that are not memorialized in prior blocks, (ii) a reference to the most recent prior block, and (iii) a record of the award of bitcoin to the miner who added the new block. In order to add blocks to the Blockchain, a miner must map an input data set (*i.e.,* a reference to the immediately preceding block in the Blockchain, plus a block of the most recent Bitcoin Network transactions and an arbitrary number called a "nonce") to a desired output data set of predetermined length ("hash value") using a cryptographic hash algorithm. To "solve" or "calculate" a block, a miner must repeat this computation with a different nonce until the miner generates a hash of a block's header that has a value less than or equal to the current target set by the Bitcoin Network. Each unique block can only be solved and added to the Blockchain by one (1) miner; therefore, all individual miners and mining pools on the Bitcoin

Network are engaged in a competitive process and are incentivized to increase their computing power to improve their likelihood of solving for new blocks.

The cryptographic hash function that a miner uses is one-way only and is, in effect, irreversible: Hash values are easy to generate from input data (*i.e.,* valid recent network transactions, Blockchain and nonce), but neither a miner nor participant is able to determine the original input data solely from the hash value. As a result, generating a new valid block with a header value less than or equal to the target prescribed by the Bitcoin Network is initially difficult for a miner, yet other nodes can easily confirm a proposed block by running the hash function just once with the proposed nonce and other input data. A miner's proposed block is added to the Blockchain once a majority of the nodes on the Bitcoin Network confirms the miner's work, and the miner that solved such block receives the reward of a fixed number of bitcoin (plus any transaction fees paid by spenders of transactions that are recorded in the block). Therefore, ''hashing'' is akin to a mathematical lottery, and miners that have devices with greater processing power (*i.e.,* the ability to make more hash calculations per second) are more likely to be successful miners because they can generate more hashes or ''entries'' into that lottery.

As more miners join the Bitcoin Network and its aggregate hashrate increases, the Bitcoin Network automatically adjusts the complexity of the block-solving equation in an effort to set distribution such that newly-created blocks will be added to the Blockchain, on average, approximately every ten (10) minutes. Hashrate is added to the Bitcoin Network at irregular rates that have grown with increasing speed since early 2013, though the rate of additional mining power slowed steadily through 2014, until the computational speed of the network temporarily and marginally declined during December 2014. The following chart, sourced from *Bitcoin.sipa.be,* shows the estimated growth of the Bitcoin Network's computational power from the first calendar quarter in 2009 to the first calendar quarter in 2016.



The rapid growth of the computational power of the Bitcoin Network means that blocks are typically solved faster than the Bitcoin protocol's target of, on average, approximately every ten (10) minutes. Although the difficulty of the mining process is adjusted on a periodic basis, after 2,016 blocks have been added to the Blockchain since the last adjustment, the average solution time for a block has been approximately 9.3 minutes for the one hundred and eighty (180) days prior to and including May 1, 2016.

Incentives for Mining

Miners dedicate substantial resources to mining. Given the increasing difficulty of the target established by the Bitcoin Network, current miners must invest in expensive mining devices with adequate processing power to hash at a competitive rate. The first mining devices were standard home computers; however, mining computers are currently designed solely for mining purposes. Such devices include application specific integrated circuit (''ASIC'') machines built by specialized companies such as BitFury. Miners also incur substantial electricity costs in order to continuously power and cool their devices while solving for a new block. In June 2013, blockchain.info estimated that the aggregate electricity costs of mining across the Bitcoin Network exceeded $300,000 every twenty-four (24) hours. Although variables such as the rate and cost of electricity are estimated, as of September 1, 2013, blockchain.info had revised upward the average 24-hour electricity cost of all mining on the Bitcoin Network to more than $1.5 million. In late 2013, blockchain.info ceased publishing estimated electric consumption on the Bitcoin Network, in part due to uncertainty in estimating electrical usage as newer, more energy efficient mining hardware became prevalent. As of May 2016, over the past year, two (2) years, and three (3) years, the aggregate hashrate of the Bitcoin Network has increased more than 3.76-fold, 22.33-fold and 17,730-fold, respectively, due in part to the development of more energy efficient ASIC mining chips and, during the second half of 2013, the substantial increase in the price of bitcoin. Additionally, it can be estimated that the scale of total computing resources devoted to mining on the Bitcoin Network is commensurate with the total rewards, which was approximately $1.6 million U.S. dollars per day as of May 1, 2016.

The Bitcoin Network is designed in such a way that the reward for adding new blocks to the Blockchain decreases over time and the production (and reward) of bitcoin will eventually cease. Once such reward ceases, it is expected that miners will demand compensation in the form of transaction fees to ensure that there is adequate incentive for them to continue mining. The amount of transaction fees will be based upon the need to provide sufficient revenue to incentivize miners, counterbalanced by the need to retain sufficient Bitcoin Network users (and transactions) to make mining profitable.

Though not free from doubt, Bitcoin industry participants have expressed a belief that transaction fees would be enforced through (i) mining operators collectively refusing to record transactions that do not include a payment of a transaction fee or (ii) the updating of Bitcoin Network software to require a minimum transaction fee payment. Indeed, most miners already have a policy regarding transactions fees, albeit the minimum fees are currently low under such policies. Under a regime whereby large miners require fees to record transactions, a transaction where the spending party did not include a payment of transaction fees would not be recorded on the Blockchain until a miner who does not require transaction fees solves for a new block (thereby recording all outstanding transaction records for which it has received data). If popular Bitcoin Network software were to require a minimum transaction fee, users of such programs would be required to include such fees; however, because of the open-source nature of the Bitcoin Network, there may be no way to require that all software instances include minimum transaction fees for spending transactions. Alternatively, a future Bitcoin Network software update could simply build a small transaction fee payment into all spending transactions (*e.g.*, by deducting a fractional number of bitcoin from all transactions on the Bitcoin Network as transaction fees).

The Bitcoin Network protocol already includes transaction fee rules and the mechanics for awarding transaction fees to the miners that solve for blocks in which the fees are recorded; however, users currently may opt not to pay transaction fees (depending on the Bitcoin Network software they use) and miners may choose not to enforce the transaction fee rules since, at present, the bitcoin rewards are far more substantial than transaction fees. As of April 2016, transaction fees accounted for an average of 1.44 percent of miners' total revenue based upon information available at *www.blockchain.info,* though the percentage of revenue represented by transaction fees is not static and fluctuates based on the number of transactions for which sending users include transaction fees, the levels of those transaction fees and the number of transactions a miner includes in its solved blocks. Typically, transactions do not have difficulty being recorded if transaction fees are not included.

Mining Pools

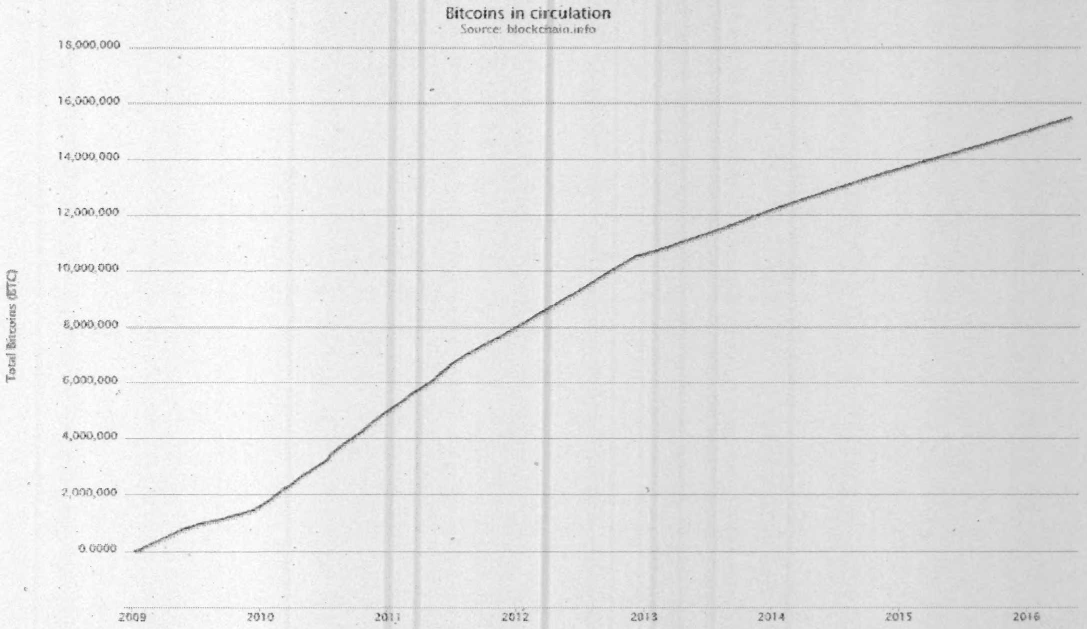
A miner's daily expected reward is proportional to their contribution to the Bitcoin Network's aggregate hashrate. Given the limited number of blocks produced per day and the statistically uncertain nature of finding blocks, a small miner acting alone would experience very high variance in block rewards. Because of this fact most miners join mining pools wherein multiple miners act cohesively and share any rewards.

According to *blockchain.info,* as of April 28, 2016, the largest three (3) known mining pools were AntPool, F2Pool and BTCC Pool, which, when aggregated, represented approximately sixty-three (63) percent of the aggregate hashrate of the Bitcoin Network (as calculated by determining the percentage of blocks mined by each such pool over the prior four (4) days). Also according to *blockchain.info,* on such date, the nine (9) largest pools (AntPool, F2Pool, BTCC Pool, BitFury, BW.COM, Slush, BitClub Network, Kano CKPool and KnCMiner) accounted for approximately ninety-seven (97) percent of the aggregate hashrate of the Bitcoin Network. In late May and early June 2014, reports indicated that a mining pool named GHash.io approached and, during a twenty-four (24)- to forty-eight (48)-hour period in early June, may have exceeded one-half of the aggregate hashrate of the Bitcoin Network, as measured by the self-reported hashrate of the pool and by measuring the percentage of blocks mined by the pool. As of April 28, 2016, GHash.io's percentage of the aggregate hashrate of the Bitcoin Network has since fallen to approximately two (2) percent. As of April 28, 2016, Antpool was determined to be the largest mining pool, having solved for twenty-eight (28) percent of the block discovered during the prior four (4) days.

Mathematically Controlled Supply

The method for creating new bitcoin is mathematically controlled in a manner so that the supply of bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of bitcoin awarded for solving a new block is automatically halved every two hundred and ten thousand (210,000) blocks. Thus, the current fixed reward for solving a new block is twenty-five (25) bitcoin per block and the reward will decrease by half to become twelve and a half (12.5) bitcoin in or around the start of July 2016 (based on estimates of the rate of block solution calculated by *BitcoinClock.com*). This deliberately controlled rate of bitcoin creation means that the number of bitcoin in existence will never exceed twenty-one (21) million and that bitcoin cannot be devalued through excessive production unless the Bitcoin Network's source code (and the underlying protocol for bitcoin issuance) is altered. See "Modifications to the Bitcoin Protocol," below. As of April 28, 2016, fifteen million, four hundred and eighty-two thousand, three hundred (15,482,300) bitcoin have been mined. It is estimated that more than ninety (90) percent of the twenty-one (21) million bitcoin will have been produced by 2022.

The following chart from *blockchain.info* indicates the number of bitcoin that have been mined since the Bitcoin Network began operation in January 2009 through April 2016.



Modifications to the Bitcoin Protocol

Bitcoin is an open source project (*i.e.,* a product whose source code is freely available to the public and that utilizes crowdsourcing to identify possible issues, problems and defects) and there is no official developer or group of developers that controls the Bitcoin Network. The Bitcoin Network's development is furthered by a collection of active contributors who can access and propose alterations to the Bitcoin Network source code hosted on *GitHub.com,* an online service and forum used to share and develop open source code. Other programmers have access to and can propose changes to the Bitcoin Network source code on *GitHub.com,* but some contributors have an elevated level of influence over the process. As a result, these contributors are responsible for quasi-official releases of updates and other changes to the Bitcoin Network's source code. Users and miners can accept any changes made to the Bitcoin Network (including those proposed by contributors) by downloading the proposed modification of the source code.

A modification of the source code is only effective with respect to the Bitcoin users and miners that download it. Consequently, as a practical matter, a modification to the source code (*e.g.,* a proposal to increase the twenty-one (21) million total limit on bitcoin or to reduce the average confirmation time target from ten (10) minutes per block) only becomes part of the Bitcoin Network if accepted by participants collectively having an effective majority of the aggregate hashrate of the Bitcoin Network. Additionally, an issue may arise in which a modification is overwhelmingly supported by users but miners do not support it, or vice versa. If a modification is accepted only by a percentage of users and miners, a division in the Bitcoin Network will occur such that one (1) network will run the pre-modification source code and the other network will run the modified source code; such a division is known as a "fork" in the Bitcoin Network. It should be noted that, although their power to amend the source code is effectively subject to the approval of users and miners, some contributors have substantial influence over the development of the Bitcoin Network and the direction of the Bitcoin community.

Bitcoin Value

Bitcoin Exchange Valuation

The value of bitcoin is determined by the value that various market participants place on bitcoin through their transactions. The most common means of determining the value of a bitcoin is by surveying one or more Bitcoin Exchanges where bitcoin is traded publicly and transparently (*i.e.,* the Bitcoin Exchange Market) or an index tracking prices on the Bitcoin Exchange Market (*e.g.,* the CoinDesk Bitcoin Price Index).

Bitcoin Exchange Public Market Data

On each online Bitcoin Exchange, bitcoin is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. Dollar, the Euro or the Chinese Yuan. Bitcoin Exchanges typically publish trade data including last price, bid and ask information, and trade volume, among other data. Although each Bitcoin Exchange has its own market price, it is expected that most Bitcoin Exchanges' market prices should be relatively consistent with the Bitcoin Exchange Market average since market participants can choose the Bitcoin Exchange on which to buy or sell bitcoin (*i.e.,* exchange shopping). Arbitrage between the prices on various Bitcoin Exchanges is possible, but varying fees and fiat currency deposit/withdrawal policies and other concerns appear to have, at times, prevented an active arbitrage mechanism among users on some Bitcoin Exchanges. For example, delayed fiat currency withdrawals imposed by Bitcoin Exchanges and the perceived risks associated with such delayed withdrawals have, at times, resulted in trading on such Bitcoin Exchange to be at a premium for certain periods.

Bitcoin Exchange Price Convergence

Price differentials across Bitcoin Exchanges remain; however, such differentials have been decreasing. For example, the daily opening price data for the one hundred (100) days prior to May 9, 2016 shows that the Bitifinex and BTC-e absolute price difference was less than 1% percent [sic] according to data from BitcoinWisdom.com. Since 2015, prices on U.S. Dollar-denominated Bitcoin Exchanges have generally been converging. In January of 2015, the average range in prices across all Bitcoin Exchanges was approximately 3.80%; as of May 2016, that figure has dropped to less than 1.30%.[18] This convergence serves to illustrate the fungibility of bitcoin across Bitcoin Exchanges and the ease with which market participants transfer their assets amongst them.

Bitcoin Exchange Market Manipulation

As the Bitcoin Exchange Market has evolved and matured, licensed entrants have emerged, including two (2) New York limited purpose trust companies, markedly changing the once concentrated and non-regulated landscape of the Bitcoin Exchange Market. For example, in the first half of 2013, Mt. Gox accounted for nearly three-quarters of all Bitcoin Exchange Market trading.[19] Any disruption to Mt. Gox trading, such as a distributed denial of service ("DDOS") attack had a dramatic impact on the bitcoin price and subsequently the Bitcoin Exchange Market as a whole. Since then, the number of constituents in the Bitcoin Exchange Market has considerably increased and no single Bitcoin Exchange represents a systemically critical part or single point of failure of the Bitcoin ecosystem. In addition, the advent of market participants who are chiefly arbitrageurs results in Bitcoin Exchange prices generally converging after dislodgement. Arbitrageurs must have funds distributed across multiple Bitcoin Exchanges in order to take advantage of temporary price dislocations, thereby discouraging the strong concentration of funds on any particular Bitcoin Exchange. As a result, the potential for manipulation on a particular Bitcoin Exchange would require overcoming the liquidity supply of such arbitrageurs who are actively eliminating any cross-market pricing differences.

The Gemini Exchange

The Gemini Exchange, an affiliate of the Sponsor, is a Digital Asset exchange that has a U.S. dollar-denominated bitcoin order book. As a facility of a New York State-chartered limited liability trust company, the Gemini Exchange is one of only two (2) Bitcoin Exchanges in the world that have such a high level of regulatory oversight. The Bitcoin Exchange Market has experienced several significant incidents at unregulated Bitcoin Exchanges and it is widely-believed that much of the self-reported trade volume numbers of unregulated Bitcoin Exchanges are inaccurate (either intentionally or unintentionally). The Gemini Exchange was established in an effort to improve the Bitcoin ecosystem by having a regulated entity where participants could engage in trading bitcoin.

In establishing the Gemini Exchange, Gemini Trust Company, LLC worked closely with the NYSDFS to obtain a limited purpose trust company license. The term "limited purpose trust company" refers to entities that are chartered under the bank and trust company provisions of the New York Banking Law. Under New York Banking Law, a "trust company" has general powers available to banks and trust companies, as well as powers generally associated with trustees and other fiduciaries.

Apart from general fiduciary powers, the following activities are among those specifically identified in the statute as activities that New York Trust Companies may conduct with respect to their fiduciary accounts, including (i) the power to accept deposits exclusively in a fiduciary capacity, to receive and disburse money, to transfer, register and countersign evidences of indebtedness or other securities, and to act as attorney in fact or agent;[20] and (ii) the power to accept appointment as receiver, trustee, or committee of the property of an estate of any person in insolvency or bankruptcy proceedings.

A "limited purpose" trust company must conduct its business and operations subject to the limitations or restrictions as the NYSDFS may prescribe in its sole discretion. In practice, most limited purpose trust companies typically engage in activities such as employee benefit trust, personal trust, corporate trust, transfer agency, securities clearance, investment management, and custodial services. A trust company, including a limited purpose trust company like Gemini Trust Company, LLC, can serve as the custodian of customer funds itself.

Under New York Banking Law, the same general procedures, requirements and criteria for the formation of a full-service bank apply also to the formation of a limited purpose trust company with two (2) exceptions: (i) No requirement to carry FDIC insurance and (ii) a level of capitalization deemed satisfactory to the Superintendent of Financial Services. Once submitted in acceptable form, a limited purpose trust company application receives the same level of scrutiny as other bank and trust company proposals and ultimately requires the approval of the Superintendent of Financial Services. In addition, trust companies are subject to many of the same requirements that apply to a bank operating under a New York State banking charter, including: (i) Capital requirements, (ii) implementation of an anti-money laundering program,[21] (iii) implementation of a cyber security program, and (iv) consumer protection disclosures.[22] Furthermore, as a limited purpose trust company with fiduciary powers under the Banking Law, all activities of a trust company, including all exchange functions, are subject to examination and supervision by the NYSDFS. Gemini Trust Company, LLC complies with the capital requirements under New York State banking law, has implemented the required anti-money laundering program and cybersecurity program and makes the required consumer protection disclosures. As a facility of a regulated entity, the Gemini Exchange is obliged to put the interests of its customers before its own, to provide accurate public market data and pricing information and to monitor for and prevent market manipulation.

---

[18] *See, e.g., https://data.bitcoinity.org/markets/price/2y/USD?c=e&t=l*).

[19] For most of 2013, Mt. Gox (a Japanese exchange operated at *www.mtgox.com* by Tibanne Co. Ltd.) was the largest online Bitcoin Exchange in the world. Supporting trading of bitcoin using sixteen (16) different fiat currencies, Mt. Gox accounted for nearly three-quarters of all Bitcoin Exchange Market trading during the first half of 2013. On February 25, 2014, Mt. Gox suspended trading on its platform and, three (3) days later, filed for bankruptcy protection in Japanese courts, stating that it had lost approximately eight hundred and fifty thousand (850,000) bitcoin, including approximately seven hundred fifty thousand (750,000) bitcoin belonging to its customers. Mt. Gox subsequently recovered access to approximately two hundred thousand (200,000) of the lost bitcoin. As no full, reliable accounting has been publicly provided, it is difficult to assess whether Mt. Gox's collapse was due to cyber-attacks (including denial of service and hacking incidents reported in 2011 and 2013), mismanagement or fraud, although many market participants believe Mt. Gox's collapse was due to the latter. Following the cessation of trading activity on its platform, Mt. Gox has been in bankruptcy proceedings in Japan and the United States and is in the process of liquidation.

[20] N.Y. Banking Law § 100 (McKinney).

[21] In particular, a prospective trust company must establish policies and procedures designed to ensure and monitor compliance with the Bank Secrecy Act ("BSA") as amended by the USA PATRIOT Act and the anti-money laundering programs of Part 115 of the General Regulations of the Banking Board. A compliance program must include, at a minimum, a system of internal controls to assure ongoing compliance, independent testing for compliance to be conducted by bank personnel or by an outside party, the designation of an individual or individuals responsible for coordinating and monitoring day-to-day compliance, and training for appropriate personnel.

[22] Limited purpose trust companies operating virtual currency exchanges are required to provide disclosures to current and prospective customers (in a form approved by NYSDFS) regarding the risks of its services and products and are also required to disclose to current and prospective customers the terms and conditions for using the trust company's products and services prior to any customer using the product or service.

As part of its supervision under the NYSDFS and New York Banking Law, Gemini Trust Company, LLC must (i) undergo semiannual bank exams, (ii) submit quarterly financial updates to NYSDFS, (iii) submit independent third-party year-end audited financial statements to NYSDFS,[23] (iv) submit semiannual Federal Financial Institutions Examination Council (“FFIEC”) Call Reports[24] to the NYSDFS, and (v) undergo an annual third-party review of its overall security program as implemented by its Chief Security Officer (“CSO”) that may take the form of a Service Organization Controls (“SOC”) Level 2 audit.

The Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust, but it may provide a convenient and stable venue given its regulatory oversight and superior liquidity characteristics. While Authorized Participants are not obliged to use the Gemini Exchange to trade their bitcoin, it may prove to be an efficient way to do so.

Gemini Exchange Spot Price

The Trust values its bitcoin as measured at 4:00 p.m. Eastern time using the Gemini Exchange Spot Price on each Business Day. The Gemini Exchange Spot Price is the price of bitcoin on the Gemini Exchange as of 4:00 p.m. Eastern time on each Business Day.

The Sponsor believes that the Gemini Exchange Spot Price is representative of the accurate price of bitcoin because of the positive price discovery attributes of the Gemini Exchange marketplace. According to market data on bitcoinity.org, as of May 23, 2016, the Gemini Exchange is a top three (3) U.S.-based Bitcoin Exchange by volume for the seven (7) days prior and had the tightest spread as a percentage of price, the tightest spread ten (10) bitcoin wide on the bid and ask, the tightest spread one hundred (100) bitcoin wide on the bid and ask and the lowest volatility (*i.e.*, smallest standard deviation) of any U.S. dollar-denominated bitcoin order book on any Bitcoin Exchange in the world. In addition, since opening in October 2015, the Gemini Exchange Spot Price differed from the median price of all U.S. Dollar-denominated Bitcoin Exchanges by 0.35% on average; that difference dropped to 0.15% on average in May 2016.[25] These facts, taken together, suggest that the Gemini Exchange Spot Price is representative and indicative of the larger Bitcoin marketplace.

As discussed above, the Gemini Exchange is uniquely positioned because of its regulatory status and licensing as a venue on which traditional financial institutions may be comfortable transacting in bitcoin. These institutions provide a vital bridge to the equities markets and other capital markets, serving to enrich price discovery, liquidity, and transparency. The Trust has entered into preliminary conversations with a number of potential Authorized Participants as well as market makers, each of which is an experienced participant in the ETP[26] marketplace and is actively engaged in trading ETPs. A number of these potential Authorized Participants, currently trade bitcoin and are already registered participants that trade on the Gemini Exchange. Authorized Participants will not be required to use the Gemini Exchange to trade their bitcoin, and the Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust. However, the Gemini Exchange may provide a convenient and stable venue in which to purchase bitcoin, as well as an efficient way to trade bitcoin, given its regulatory oversight and superior liquidity characteristics.[27] See “Bitcoin Value—The Gemini Exchange” above.

Bitcoin Market

Global Bitcoin Market

Global trade in bitcoin consists of individual end-user-to-end-user transactions, together with facilitated exchange-based bitcoin trading on “lit” markets as well as “dark pools”. A limited market currently exists for bitcoin-based derivatives. The Trust represents the first known ETP in the United States that seeks to track the price of a Digital Asset (a “Digital Asset ETP”). Securitized instruments have been created for other marketplaces, but have encountered limited success due to their lack of transparency and thorough regulatory oversight. Two notable examples are the Grayscale Investment Trust, which trades under the ticker GBTC on OTC Markets (formerly the “Pink Sheets”) and does not qualify as an exchange-listed product, and Bitcoin Tracker One, which trades under the ticker COINXBT on the Stockholm Stock Exchange. Neither of these instruments are held to the same regulatory scrutiny and oversight as a security listed under the Securities Act. Because of the high standards pursued in the creation and listing of the Trust, it will finally provide investors with a reliable and transparent vehicle for access to bitcoin as an asset class.

End-User-to-End-User

The Bitcoin end-user-to-end-user ecosystem operates on a continuous, 24-hour per day basis. This is accomplished through decentralized peer-to-peer transactions between parties on a principal-to-principal basis. All risks and issues of credit are between the parties directly involved in the transaction. Liquidity can change from time to time during the course of a 24-hour trading day. The Bitcoin Network rules that require transaction fees are generally not enforced; therefore transaction costs, if any, are negotiable between the parties and may vary widely, although, where transaction fees are included, they are paid by the spending party in a Bitcoin transaction. These transactions occur remotely through the Internet or in-person through forums such as Satoshi Square (an open-air bitcoin trading market held in New York City) and bulletin boards such as LocalBitcoins. Marketplaces like LocalBitcoins and ICBIT are intended to bring together counterparties trading in bitcoin but do not provide any clearing or intermediary function and may or may not report transaction data such as price and volume.

Bitcoin Exchange “Lit” Market

Online Bitcoin Exchanges traded over $450,000,000 dollars of notional value during a twenty-four (24) hour period on May 31, 2016.[28] These marketplaces provide significant data with respect to prevailing valuations of bitcoin. Most Bitcoin Exchanges operate through pooled account systems, whereby the users of the Bitcoin Exchange send bitcoin and/or fiat currency to an account of the Bitcoin Exchange, which records user sub-account balances in a ledger entry system. Trades on pooled account exchanges are typically conducted "off-Blockchain," meaning that they are settled by reallocating bitcoin and money to and from users on the balanced ledger of the Bitcoin Exchange. Therefore, a trade on a pooled account exchange will not result in a Bitcoin transaction being transmitted and subsequently recorded on the Blockchain, or of a money transfer going from one bank account to another. For a pooled-account Bitcoin Exchange, Bitcoin transactions and money transfers typically only occur during the withdrawal or deposit of bitcoin or fiat currency by an exchange customer, or if the Bitcoin Exchange needs to shift bitcoin or fiat currency between its pooled accounts for internal purposes. Nevertheless, Bitcoin Exchanges typically publish trade data including last price, bid and ask information, and trade volume, among other data, on their respective Web sites and through application programming interfaces ("APIs").

---

[23] Gemini Trust Company, LLC, successfully completed an independent third-party opening day Balance Sheet audit for October 2, 2015 as well as an independent third-party year-end Financial Statements audit for December 31, 2015. No material issues, weaknesses or concerns were raised.

[24] Gemini Trust Company, LLC, successfully completed and filed its first FFIEC Call Report with the NYSDFS on February 1, 2016.

[25] *Id.*

[26] For purposes of this filing, the term ETP means any product that may be listed on the Exchange pursuant to Rule 14.11.

[27] *See, e.g., https://data.bitcoinity.org/markets/exchanges/USD/30d#volatility_asc.*

[28] *See, e.g., https://data.bitcoinity.org/markets/volume/30d?c=e&t=a.*

As noted above, Gemini Exchange, an affiliate of the Sponsor and the source of the Gemini Exchange Spot Price used by the Trust to calculate its NAV, operates the Web site *www.gemini.com.* Gemini Exchange is owned and operated by Gemini Trust Company, LLC, the Trust's Custodian. As a facility of a New York State-chartered limited liability trust company, Gemini Exchange operates under the direct supervision and regulatory authority of the NYSDFS. The Gemini Trust Company is a fiduciary and must meet the capitalization, compliance, anti-money laundering, consumer protection and cyber security requirements as set forth by the NYSDFS. Gemini Exchange's principal business is to provide an electronic trading platform and associated online presence to allow customers to exchange fiat currency (*e.g.,* U.S. Dollars) for Digital Assets (*e.g.,* bitcoin or ether) and vice versa.

Bitcoin Exchange Market "Dark Pools" and OTC Trading

In addition to transparent or "lit" online Bitcoin Exchanges with a traditional central limit order book structure, some trading in bitcoin takes place on an on-demand or over-the-counter ("OTC") basis. Similar to mature securities, there are also private request for quote (RFQ) venues and "dark pools," which are bitcoin trading platforms that do not publicly report limit order book data. Market participants have the ability to execute large block trades in a dark pool without revealing those trades and the related price data to the public Bitcoin Exchange Market; however, any withdrawal from or deposit to a dark pool platform must ultimately be recorded on the Blockchain, as must OTC transactions. Genesis Trading also operates a form of dark pool through a trading desk that buys and sells blocks of bitcoin without publicly reporting trade data. In June 2015, Kraken, a Bitcoin Exchange, launched a dark pool for bitcoin trades separate from its public central limit order book. Informal dark pools are currently believed to exist, particularly among wholesale buyers of bitcoin and Bitcoin Network mining groups that obtain bitcoin through mining. Such informal dark pools function as a result of the peer-to-peer nature of the Bitcoin Network, which allows direct transactions between any seller and buyer. As the Bitcoin Exchange Market and bitcoin dark pools have a limited history and no publicly available limit order book data, it is difficult to estimate the impact of dark pools on the Bitcoin Exchange Market.

Global Bitcoin Derivatives Markets

Nascent derivatives markets for bitcoin now exist. For example, certain types of options, futures contracts for differences and other derivative instruments are available in certain jurisdictions; however, many of these are not available in the United States and generally are not regulated to the degree that U.S. investors expect derivative instruments to be regulated. The U.S. Commodity Futures Trading Commission ("CFTC") has approved TeraExchange, LLC as a swap execution facility ("SEF"), on which bitcoin swap contracts may be entered into. On October 9, 2014, TeraExchange announced that it had hosted the first executed bitcoin swap traded on a CFTC-regulated platform. Additionally, in September 2015, the CFTC issued an order temporarily registering LedgerX LLC as a SEF. LedgerX also previously applied for registration as a derivatives clearing organization ("DCO") although its application is still in the process of CFTC approval. Other parties have acknowledged submitting applications for registration to the CFTC, though no other bitcoin-focused derivatives platform has been approved for registration by the CFTC. Various platforms and Bitcoin Exchanges also offer trading on margin. Currently, the open interest in these bitcoin derivative instruments is quite limited in comparison to the volume of actual bitcoin trades. CFTC commissioners have previously expressed publicly that derivatives based on Digital Assets such as bitcoin are subject to regulation by the CFTC, including oversight to prevent market manipulation of the price of bitcoin. As previously noted, in the September 2015 Coinflip case, the CFTC instituted and settled administrative proceedings that involved a bitcoin derivatives trading platform and its chief executive officer. In Coinflip,[29] the CFTC determined that bitcoin and other "virtual currencies" (aka Digital Assets) are properly defined as commodities under the CEA and CFTC regulations, and applied CEA provisions and CFTC regulations that apply to transactions in commodity options and swaps to the conduct of the bitcoin derivatives trading platform. The CFTC affirmed its approach to the regulation of bitcoin and bitcoin-related enterprises on June 2, 2016, when the CFTC settled charges against Bitfinex, a Bitcoin Exchange based in Hong Kong. In its Order, the CFTC found that Bitfinex engaged in "illegal, off-exchange commodity transactions and failed to register as a futures commission merchant" when it facilitated borrowing transactions among its users to permit the trading of bitcoin on a "leveraged, margined or financed basis" without first registering with the CFTC.[30] While the Commission has not opined on the legal characterization of bitcoin as a security, it has taken various actions against persons or entities misusing bitcoin in connection with fraudulent schemes (*i.e.,* Ponzi schemes), inaccurate and inadequate publicly disseminated information, and the offering of unregistered securities.[31]

---

[29] *See supra* note 13.

[30] *See In re* BFXNA Inc., No. 16–19 (CFTC June 2, 2016), available at: *http://www.cftc.gov/idc/groups/public/@lrenforcementactions/documents/legalpleading/enfbfxnaorder060216.pdf.*

[31] *See, e.g.,* Complaint and Demand for Jury Trial, *SEC* v. *Homero Joshua Garza, GAW Miners, LLC and ZenMiner, LLC,* Case 3:15–cv–01760 (D. Conn. Dec. 1, 2015) (The Commission brought charges in connection with a bitcoin-related Ponzi scheme); *SEC* v. *Erik T. Voorhees,* SEC Administrative Proceeding File No. 3–15902 (June 3, 2014), available at *https://www.sec.gov/litigation/admin/2014/33-9592.pdf* (The Commission brought an administrative action in connection with the offering of unregistered securities of two bitcoin-related entities.); BTC Trading, Corp. and Ethan Burnside, Securities Act Release No. 9685 (Dec. 8, 2014), available at *http://www.sec.gov/litigation/admin/2014/33-9685.pdf* (The Commission brought an administrative action in connection with the operation and offering of securities of two online exchanges, neither of which were registered with the Commission, that accepted payment in bitcoin and primarily listed virtual currency-related companies.); *SEC* v. *Sand Hill Exchange, et al.,* Securities Act Release No. 9809 (June 17, 2015), available at *https://www.sec.gov/litigation/admin/2015/33-9809.pdf* (The Commission took legal action against an online exchange that accepted payment in bitcoin in connection with disseminating fraudulent information, among other matters.).

Goods and Services

Bitcoin can also be used to purchase goods and services, either online or at physical locations, although reliable data is not readily available about the retail and commercial market penetration of the Bitcoin Network. In January 2014, U.S. national online retailers Overstock.com and TigerDirect began accepting Bitcoin payments. Over the course of 2014, computer hardware and software company Microsoft began accepting bitcoin as online payment for certain digital content, online retailer NewEgg began accepting bitcoin, and computer hardware company Dell began accepting bitcoin. There are thousands of additional online merchants that accept bitcoin, and the variety of goods and services for which bitcoin can be exchanged is increasing. Currently, local, regional and national businesses, including Time Inc., Wikimedia, WordPress, Expedia and Foodler, accept bitcoin. Bitcoin service providers such as BitPay, Coinbase and GoCoin and online gift card retailer Gyft provide other means to spend bitcoin for goods and services at additional retailers. There are also many real-world locations that accept bitcoin throughout the world.

As of April 2016, it was estimated that as many as one hundred thousand (100,000) merchants or businesses accept, or have the technological infrastructure to choose to accept (*e.g.,* Shopify merchants), bitcoin as payment. In September 2014, payments giant PayPal announced a partnership with BitPay, Coinbase and GoCoin to expand their Bitcoin-related services to PayPal's merchant customers, thereby significantly expanding the reach of bitcoin-accepting merchants. To date, the rate of consumer adoption and use of bitcoin in paying merchants has trailed the broad expansion of retail and commercial acceptance of bitcoin. Nevertheless, there will likely be a strong correlation between continued expansion of the Bitcoin Network and its retail and commercial market penetration.

Market Participants

Miners

Miners range from Bitcoin enthusiasts to professional mining operations that design and build dedicated machines and data centers, but the vast majority of mining is now undertaken by participants in mining pools. See "Bitcoin Mining & Creation of New Bitcoin" above.

Investment and Speculative Sector

This sector includes the investment and trading activities of both private and professional investors and speculators. These participants range from exchange-traded products, such as ARK Web x.0 ETF, or hedge funds such as the Pantera Bitcoin Fund Ltd. to day-traders who invest in bitcoin by trading on Bitcoin Exchanges such as Slovenia-based BitStamp and Hong Kong-based Bitfinex. *See* "Uses of Bitcoin—Bitcoin Exchange Market" below.

Historically, larger financial services institutions are publicly reported to have limited involvement in investment and trading in bitcoin. In December 2013, Wedbush Securities and Bank of America Merrill Lynch released preliminary research reports on Bitcoin as both a payment tool and investment vehicle. Additionally in December, the Federal Reserve Bank of Chicago released a primer on Bitcoin prepared by a senior economist. In early 2014, Fitch Ratings, Goldman Sachs, JPMorgan Chase, PricewaterhouseCoopers, UBS Securities and Wedbush Securities, among others, released additional research reports analyzing the Bitcoin Network on the basis of bitcoin value, technological innovation or payment system mechanics. In December 2014, the Federal Reserve Board's Divisions of Research & Statistics and Monetary Affairs released an analysis of the Bitcoin Network's transaction system and the Bitcoin Exchange Market's economics. Additionally, institutions including Fortress Investment Group and Pantera Capital made, or proposed to make, direct or indirect investments in bitcoin or the Bitcoin ecosystem. In addition, in October 2015, the Congressional Research Service, at the request of one (1) or more Members, released a report detailing the background and regulatory landscape of Bitcoin.

Retail Sector

The retail sector includes users transacting in direct peer-to-peer Bitcoin transactions through the direct sending of bitcoin over the Bitcoin Network. The retail sector also includes transactions between consumers paying for goods or services from commercial or service businesses through direct transactions or third-party service providers such as BitPay, Coinbase and GoCoin. BitPay, Coinbase and GoCoin each provide a merchant platform for instantaneous transactions whereby the consumer sends bitcoin to BitPay, Coinbase, or GoCoin, which then provides either the bitcoin or the cash value thereof to the commercial or service business utilizing the platform. PayPal, Square and Shopify are examples of traditional merchant payment processors or merchant platforms that have also added Bitcoin payment options for their merchant customers. Payment processing through the Bitcoin Network typically reduces the transaction cost for merchants, relative to the costs paid for credit card transaction processing. Consumers can now purchase goods or services through retail companies such as Overstock.com, DISH, Dell, Expedia, Microsoft, and Time, Inc.

Service Sector

This sector includes companies that provide a variety of services including the buying, selling, payment processing and storing of bitcoin. Bitfinex, Bit-X and BTC-e are three (3) of the largest global U.S. Dollar-denominated Bitcoin Exchanges in the world based on Bitcoinity.org as of May 3, 2016. Huobi and OKCoin are large Bitcoin Exchanges based in China that primarily feature trading of bitcoin for Chinese Yuan based on Bitcoinity.org as of May 3, 2016. Coinbase and Circle are each multi-service financial institutions that provide digital wallets that store bitcoin for users and also serve as a retail gateway whereby users can purchase bitcoin for fiat currency. Coinbase, BitPay, BitPagos, and GoCoin are examples of Bitcoin payment processors that allow merchants to accept bitcoin as payment.

As the Bitcoin Network continues to grow in acceptance, it is anticipated that service providers will expand the currently available range of services and that additional parties will enter the service sector for the Bitcoin Network.

Competition

Bitcoin is not the only Digital Asset founded on math-based algorithms and cryptographic security, although it is considered the most prominent. Approximately seven hundred (700) other Digital Assets or "altcoins" have been developed since the Bitcoin Network's inception, including Litecoin, Ether and Ripple. The Bitcoin Network, however, possesses the "first-to-market" advantage and thus far has the largest market capitalization and is secured by a mining network with significantly more aggregate hashrate than the networks of any other Digital Assets.

Description of the Trust and the Shares

According to the Registration Statement, the investment objective of the Trust is for the Shares to track the price of bitcoin as measured at 4:00 p.m. Eastern time using the Gemini Exchange

Spot Price on each Business Day, less the Trust's liabilities (which include accrued but unpaid fees and expenses).[32] The Shares are designed for investors seeking a cost-effective and convenient means of gaining investment exposure to bitcoin similar to a direct investment in bitcoin. A substantial direct investment in bitcoin may require expensive and sometimes complicated arrangements in connection with the acquisition, security and safekeeping of the bitcoin and may involve the payment of substantial fees to acquire such bitcoin from third-party facilitators through cash payments of U.S. Dollars. Although the Shares will not be the exact equivalent of a direct investment in bitcoin, they provide investors with an alternative that allows them to gain investment exposure to bitcoin. In addition, the Trust will provide its investors with other advantages including easy accessibility, relative cost efficiencies and minimal credit risk as the Trust will wholly-own all of its bitcoin assets, as discussed below. The Shares offer an investment that is:

- *Easily Accessible and Relatively Cost Efficient.* Investors in the Shares can also directly access bitcoin through the Bitcoin Exchange Market. The Sponsor believes that investors will be able to more effectively implement strategic and tactical asset allocation strategies that use bitcoin by using the Shares instead of directly purchasing and holding bitcoin, and for many investors, transaction costs related to the Shares will be lower than those associated with the direct purchase, storage and safekeeping of bitcoin.
- *Exchange-Traded and Transparent.* The Shares will be listed and trade on BZX, providing investors with an efficient means to implement various investment strategies. Upon effectiveness of the registration statement of which this prospectus is a part, the Shares will be eligible for margin accounts and will be backed by the assets of the Trust. The Trust will not hold or employ any derivative securities. The value of the Trust's holdings will be reported each day on the Trust's Web site. Furthermore, the fact that the Trust will be regulated by the Exchange and by the Commission under the Act provides a level of oversight not provided by any other current Bitcoin Exchanges or service providers. The Sponsor represents that the Trust will enter into an information sharing agreement with the Gemini Exchange enabling it to obtain and publish the Gemini Exchange Spot Price on the Trust's Web site. In addition, the Sponsor will arrange for the Gemini Exchange to share data regarding the Gemini Exchange Spot Price and other trading data with the Exchange. See "Overview of the Bitcoin Industry and Market—Bitcoin Value—Gemini Exchange Spot Price" above. Lastly, the Exchange has the ability to halt trading and delist the Shares of the Trust under certain circumstances and, more generally, retains broad discretionary authority over the continued listing of securities on the Exchange, as further described below.
- *Proprietary Cold Storage System.* The Custodian has been appointed to store and safekeep the Trust's bitcoin using a state-of-the-art, proprietary Cold Storage System. Similar hardware, software, administration and continued technological development may not be available or cost-efficient for many investors. Winklevoss IP, LLC ("WIP") is the owner of certain intellectual property and it has licensed such intellectual property to the Sponsor for use by the Custodian and its service providers in the safekeeping of the Trust's bitcoin.

Using the precious metals exchange-traded trusts currently trading on U.S. exchanges [33] as design paradigms, the Sponsor has structured the Trust to be a similar passive investment vehicle holding a single asset. Like the precious metals exchange traded trusts cited above, the Trust will only own and store bitcoin and will not be permitted to hold cash or any other Digital Asset.

The Custodian has been appointed to store and safekeep the Trust's bitcoin using a state-of-the-art, proprietary Cold Storage System.[34] Similar hardware, software, administration and continued technological development may not be available or cost-efficient for many investors. As such, the logistics of accepting, transferring and safekeeping of actual bitcoin are dealt with by the Custodian using the Cold Storage System, and the related expenses are built into the price of the Shares. Therefore, the investor does not have any additional tasks or costs over and above those associated with dealing in any other publicly traded security. The Shares are intended to provide investors with a cost-efficient and convenient means of gaining exposure to bitcoin similar to a direct investment in bitcoin.

All bitcoin is recorded on the Blockchain, the decentralized transaction ledger of the Bitcoin Network. The Blockchain is a canonical record of every bitcoin, every Bitcoin transaction (including the mining of new bitcoin) and every Bitcoin address associated with a quantity of bitcoin. In order to transfer or "spend" bitcoin, one must control the private key that is mathematically associated with a given Bitcoin address. The private keys that control the Trust's bitcoin are secured by the Custodian and stored completely offline (*i.e.*, air-gapped) using the Custodian's state-of-the-art, proprietary Cold Storage System. The Custodian's Cold Storage System is founded on the principles of (i) building defense-in-depth against external threats; (ii) protecting against human error; and (iii) guarding against misuse of insider access.

---

[32] According to the Registration Statement, the activities of the Trust will be limited to (1) issuing Baskets in exchange for the actual bitcoin deposited by the Authorized Participants with the Custodian as consideration, (2) transferring actual bitcoin as necessary to cover the Sponsor's Fee and as necessary to pay Trust expenses not assumed by the Sponsor and other liabilities, (3) transferring actual bitcoin in exchange for Baskets surrendered for redemption by the Authorized Participants, (4) causing the Administrator to sell bitcoin on the termination of the Trust, and (5) engaging in all administrative and custodial procedures necessary to accomplish such activities in accordance with the provisions of the Trust Agreement, the Trust Servicing Agreement, the Trust Agency Service Provider Agreement, the Custody Agreement, the License Agreement and Authorized Participant Agreements. The Trust will not be actively managed. It will not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the market prices of bitcoin. The Trust seeks to achieve its investment objective by directly owning bitcoin and will not speculate with regard to short-term changes in bitcoin prices. The Trust will not invest in bitcoin derivatives, futures, swaps, or other financial instruments that represent bitcoin or that may be exchanged for bitcoin. The Trust does not expect to make any cash distributions to shareholders.

[33] *See, e.g.*, SPDR Gold Trust: *See* Securities Exchange Act Release No. 50603 (October 28, 2004), 69 FR 64614 (November 5, 2004) (SR–NYSE–2004–22) (approving listing of the SPDR Gold Trust); iShares Gold Trust: *See* Securities Exchange Act Release No. 51058 (January 19, 2005), 70 FR 3749 (January 26, 2005) (SR–Amex–2004–38) (approving listing of the iShares Gold Trust); ETFS Gold Trust: *See* Securities Exchange Act Release No. 59895 (May 8, 2009), 74 FR 22993 (May 15, 2009) (SR–NYSEArca–2009–40) (approving listing of the ETFS Gold Trust); ETFS Silver Trust: *See* Securities Exchange Act Release No. 59781 (April 17, 2009), 74 FR 18771 (April 24, 2009) (SR–NYSEArca–2009–95) (approving listing of the ETFS Silver Trust); ETFS Platinum Trust: *See* Securities Exchange Act Release No. 61219 (December 22, 2009), 74 FR 68886 (December 29, 2009) (SR–NYSEArca–2009–94) (approving listing of the ETFS Platinum Trust); and ETFS Palladium Trust: *See* Securities Exchange Act Release No. 61220 (December 22, 2009), 74 FR 68895 (December 29, 2009) (SR–NYSEArca–2009–94) (approving listing of the ETFS Palladium Trust).

[34] WIP is the owner of certain intellectual property and it has licensed such intellectual property to the Sponsor for use by the Custodian and its service providers in the safekeeping of the Trust's bitcoin. The Sponsor believes that the use of this Cold Storage System and other security features described below, the technological experience of the Custodian's employees and the Sponsor's management team, as well as the use of independent auditors for periodic reviews, will provide a level of security not available through other Digital Asset custodians.

In order to accomplish these principles, the Custodian's Cold Storage System generates, stores and manages the private keys that control the Trust's bitcoin onboard hardware security modules ("HSMs") for the lifetime of each private key. HSMs (each, a "Signer") are tamper-resistant computers used by the Custodian to digitally sign (*i.e.,* authenticate) any transfer of the Trust's bitcoin. All Signers are stored, as well as backed up, in various geographically distributed, access-controlled facilities throughout the United States. In addition, the Custodian's Cold Storage System utilizes multiple-signature ("Multisig") technology with an "M-of-N" signing design that requires a signature from more than one (1) Signer (but fewer than the full complement of potential Signers) in order to move the Trust's bitcoin. This provides both security against attacks and tolerance to losing access to a minority of facilities or private keys, thereby eliminating single points of failure. In addition, the operation of a Signer requires the coordinated actions of multiple employees (each a "Signatory") to protect against insider malfeasance. Lastly, the Cold Storage System is comprised of hardware that is sourced from multiple, diverse manufacturers to guard against supply-chain risks.

The Custodian's Cold Storage System was purpose-built to demonstrate "proof of control" of the private keys associated with its public Bitcoin addresses. More specifically, the Custodian can use Signers to sign a specific message chosen by the Custodian that references a current event (*i.e.,* to prove recency), thereby proving control of the private keys associated with the public Bitcoin addresses in which the Trust's bitcoin are held. This allows the Custodian to evidence control of the Trust's assets periodically during audits on-demand and without necessitating the transfer of any of the Trust's bitcoin.

The Custodian has evaluated different insurance policy options and determined not to obtain coverage at this time due to insurers' lack of understanding and sophistication with respect to Digital Assets, which has led to a thin marketplace of policies that are (i) not priced in an actuarially-fair manner and (ii) don't properly model relevant loss vectors. Unfortunately, an efficient and effective marketplace for bitcoin insurance has not yet developed.

The Custodian is the custodian of the Trust's bitcoin in accordance with the terms and provisions of the Trust Custody Agreement and utilizes its Cold Storage System in the administration and operation of the Trust and the safekeeping of its bitcoin. The Custodian segregates the Trust's bitcoin which are held in unique Bitcoin addresses with balances that can be directly verified on the Bitcoin Blockchain. Under the Trust Custody Agreement, the Custodian is also responsible for the maintenance of, and periodic updates to, the Cold Storage System.

Acting on standing instructions specified in the Trust Custody Agreement, the Custodian will accept, on behalf of the Trust, delivery of bitcoin from Authorized Participants into the Trust Custody Account in the creation of a Basket. In order for an Authorized Participant to redeem a Basket and receive a distribution of bitcoin from the Trust, the Custodian, upon receiving instructions from the Administrator, will sign transactions necessary to transfer bitcoin out of the Trust Custody Account and distribute to the Bitcoin address specified by the Authorized Participant. See "Net Asset Value—Creation and Redemption of Shares."

The Sponsor has adopted several control procedures in addition to the safety features integral to the Cold Storage System's design. For example, the Sponsor must engage an independent audit firm to periodically audit the Custodian's Cold Storage System protocols and internal controls ("Internal Controls Audit"), and report to the Sponsor at least annually on such matters. Additionally, the Sponsor must engage an independent audit firm to biannually verify that the Custodian can demonstrate "proof of control" of the private keys that control the Trust's bitcoin ("Proof of Control Audit"). One Proof of Control Audit will be conducted at the end of each calendar year and the other at random.

Net Asset Value

According to the Registration Statement, on each Business Day, the Administrator will use the Gemini Exchange Spot Price as measured at 4:00 p.m. Eastern time (the "Evaluation Time") to calculate the Trust's NAV.

At the Evaluation Time, the Administrator will value the bitcoin held by the Trust using the Gemini Exchange Spot Price or such other publicly available price as the Sponsor in good faith may deem fairly represents the fair market value of the Trust's bitcoin. In the event that the Sponsor determines that the Gemini Exchange Spot Price is not an appropriate basis for evaluation of the Trust's bitcoin, the Sponsor will instruct the Administrator to use the spot price of the itBit bitcoin exchange (the "itBit Exchange") as an alternative basis for calculating the Trust's NAV. The itBit Exchange is operated by the itBit Trust Company, LLC, a New York State-chartered limited liability trust company that, like the Gemini Exchange, operates under the direct supervision and regulatory oversight of the NYSDFS. Any determination that the Gemini Exchange Spot Price is unavailable or otherwise not an appropriate basis for calculating the Trust's NAV would be based upon extraordinary criteria in which the operation of Gemini Exchange is disrupted or otherwise experiencing material calculation or reporting irregularities. If the Sponsor determines in good faith that neither the Gemini Exchange Spot Price nor the spot price on the itBit Exchange is reliable for calculating the Trust's NAV on a particular Business Day, including but not limited to situations where it does not reflect material events occurring between the time of calculation of such Gemini Exchange Spot Price or the spot price on the itBit Exchange and the time the Trust's Shares are valued, bitcoin will be valued using fair market value pricing as determined in good faith by the Sponsor and calculated by the Administrator under procedures established in the Trust Servicing Agreement. Determining the fair market value of bitcoin involves the consideration of a number of subjective factors and thus the prices for bitcoin may differ from the Gemini Exchange Spot Price or the spot price on the itBit Exchange. The Sponsor may consider the market price for bitcoin on other Bitcoin Exchanges, or in other forums for which bitcoin prices are published publicly. Neither the Administrator nor the Sponsor shall be liable to any person for the determination that the Gemini Exchange Spot Price or an alternative basis for a fair market value of bitcoin is not appropriate as a basis for calculation of the Trust's NAV provided that such determination is made in good faith.

In order to calculate the Trust's NAV, the Administrator will first determine the value of the Trust's bitcoin and then subtract all of the Trust's liabilities (including accrued but unpaid fees and expenses) to determine the Trust's net assets. The Administrator will calculate the Trust's NAV by dividing the net assets of the Trust by the number of the Shares outstanding as of the close of trading on the Exchange (which includes the net number of any of the Shares created or redeemed on such Business Day).

The Sponsor will publish the Trust's NAV on the Trust's Web site as soon as practicable after determination by the Administrator. To the extent that the NAV has been calculated using a price per bitcoin other than the Gemini Exchange Spot Price for such Business Day, the publication on the Trust's Web site will note the valuation methodology and the price per bitcoin resulting from such calculation.

Creation and Redemption of Shares

The Trust is expected to issue and redeem Shares from time to time only in one or more whole Baskets. The Trust will issue and redeem the Shares in Baskets only to certain Authorized Participants on an ongoing basis. On a creation, Baskets will be distributed to the Authorized Participants by the Trust in exchange for the delivery to the Trust of the appropriate number of bitcoin (*i.e.,* bitcoin equal in value to the value of the Shares being purchased). On a redemption, the Trust will distribute bitcoin equal in value to the value of the Shares being redeemed to the redeeming Authorized Participant in exchange for the delivery to the Trust of one or more Baskets. On each Business Day, the value of each Basket accepted by the Administrator in a creation or redemption transaction will be the same (*i.e.,* each Basket will consist of 50,000 Shares and the value of the Basket will be equal to the value of 50,000 Shares at their net asset value per Share on that day). The Trust will not issue or redeem fractions of a Basket.

Only Authorized Participants will be able to place orders to create or redeem Baskets. Authorized Participants must be (i) registered broker-dealers or other securities market participants, such as banks and other financial institutions, which are not required to register as broker-dealers to engage in securities transactions, and (ii) DTC Participants. A Transaction Fee may be imposed to offset the transfer and other transaction costs associated with creation or redemption. Authorized Participants or their affiliated market makers are expected to have the facility to participate directly on one or more Bitcoin Exchanges.

The Trust currently expects that prior to the commencement of trading on the Exchange, at least two Authorized Participants will have signed an Authorized Participant Agreement with the Trust and may create and redeem Baskets as described above. Persons interested in placing orders to create or redeem Baskets should contact the Sponsor or the Administrator to obtain the contact information for the Authorized Participants. Shareholders who are not Authorized Participants will only be able to redeem their Shares through an Authorized Participant.

Bitcoin will be (i) delivered to the Trust Custody Account from an Authorized Participant in connection with the creation of one or more Baskets and (ii) distributed by the Custodian from the Trust Custody Account to the Authorized Participant in connection with the redemption of one or more Baskets.

Under the Authorized Participant Agreement, the Sponsor has agreed to indemnify the Authorized Participants against certain liabilities, including liabilities under the Securities Act.

The following description of the procedures for the creation and redemption of Baskets is only a summary and an investor should refer to the relevant provisions of the Trust Agreement, the Trust Servicing Agreement and the form of Authorized Participant Agreement for more detail, each of which is attached as an exhibit to the Registration Statement of which the prospectus is a part.

Creation Procedures

On any Business Day, an Authorized Participant may place an order with the Administrator to create one or more Baskets (each a "Creation Basket"). The settlement of Creation Basket orders, including the delivery of bitcoin by the Authorized Participant and distribution of Shares to the Authorized Participant, will occur only on days BZX is open for regular trading.

Creation Basket Order Requirements

The number of bitcoin required to be delivered to the Trust in exchange for a Creation Basket is determined by the Trust Agreement. All questions as to the amount of bitcoin necessary to deliver to purchase a Creation Basket will be conclusively determined by the Administrator. The Administrator's determination of the cost of a Creation Basket shall be final and binding on all persons interested in the Trust.

Creation Basket Distribution

An Authorized Participant who places a Creation Basket order with the Administrator is responsible for delivering the bitcoin to the Trust required to purchase the Creation Basket on the order date. Bitcoin delivered by an Authorized Participant will be considered settled upon the completion of the Confirmation Protocol. Under the Confirmation Protocol, the Custodian must wait until the bitcoin delivery transaction has been confirmed by six (6) consecutive blocks on the Blockchain before it is considered settled. The confirmation process should take approximately one (1) hour depending upon the speed with which Bitcoin Network miners add new blocks to the Blockchain. See "Overview of the Bitcoin Industry and Market—Cryptographic Security Used in the Bitcoin Network—Double-Spending and the Bitcoin Network Confirmation System," above. An Authorized Participant shall not be deemed to have fulfilled its bitcoin delivery requirement until the completion of the Confirmation Protocol.

Following confirmation of the receipt of bitcoin into the Trust Custody Account by the Custodian, the Administrator will direct DTC to credit the Authorized Participant's DTC account with the Shares representing the number of Creation Baskets purchased. The expense and risk of delivery, ownership and safekeeping of a bitcoin delivery until it has been received by the Trust in the Trust Custody Account shall be borne solely by the Authorized Participant.

The Custodian may accept delivery of bitcoin by such other means as the Sponsor, from time to time, may determine to be acceptable for the Trust, provided that the same is disclosed in a prospectus relating to the Trust filed with the Commission pursuant to Rule 424 under the Securities Act. If bitcoin is to be delivered other than as described above, the Sponsor is authorized to establish such procedures and to appoint such custodians and establish such custody accounts in addition to those described in this prospectus, as the Sponsor determines to be desirable.

Suspension or Rejection of Creation Basket Orders

The Administrator may, in its discretion, and when directed by the Sponsor, suspend the right to place Creation Basket orders, or postpone the Creation Basket settlement date, (i) for any period during which BZX is closed other than customary weekend or holiday closings, or trading on BZX is suspended or restricted or (ii) for any period during which an emergency exists as a result of which receipt or evaluation of bitcoin delivery is not reasonably practicable or presents, in the judgment of the Administrator, the Custodian or the Sponsor or their agents, a security risk to the Cold Storage System. The inability of the Custodian to operate the Cold Storage System because of a failure of hardware, software or personnel or an inability to access the Cold Storage System (*e.g.,* because of power failure or acts of God) are examples of such emergencies. None of the Administrator, the Custodian, the

Sponsor or their agents will be liable to any person or in any way for any loss or damages that may result from any such suspension or postponement.

The Administrator may also reject a Creation Basket order if (i) such order is not presented in proper form as described in the Authorized Participant Agreements, (ii) such order is incorrect, (iii) if the Creation Basket Order presents, in the opinion of the Administrator, the Custodian, the Sponsor, or their agents, a security risk to the Cold Storage System, or (iv) the fulfillment of the Creation Basket order, in the opinion of counsel, might be unlawful. None of the Trustee, Administrator, Trust Agency Service Provider, Custodian, Sponsor, or their agents, will be liable for the rejection of any Creation Basket order.

Redemption Procedures

The procedures by which an Authorized Participant can redeem one or more Baskets (each a ''Redemption Basket'') will mirror the procedures for the creation of Baskets. On any Business Day, an Authorized Participant may place a Redemption Basket order with the Administrator. The settlement of Redemption Baskets orders, including the delivery of Shares to the Trust and distribution of bitcoin to the Authorized Participant, will only occur when BZX is open for regular trading. Settlement of Redemption Baskets orders may be delayed longer than three (3), but no more than five (5), Business Days following the Redemption Basket order date. Settlement of Redemption Baskets may be delayed only in the instance of administrative or custodial delays in the processing of a distribution of bitcoin from the Trust Custody Account, whether by reason of Bitcoin Network delays, mechanical or clerical error or by act of God. Settlement of a Redemption Basket will occur only on Business Days. Redemption Basket orders must be placed no later than 4:00 p.m. Eastern time on a Business Day. A Redemption Basket order so received will be effective on the date it is received if the Administrator finds it to be in satisfactory form. The redemption procedures allow only Authorized Participants to place Redemption Basket orders and do not entitle an Authorized Participant to receive a distribution of bitcoin in an amount that is different than the value of a Redemption Basket.

By placing a Redemption Basket order, an Authorized Participant agrees to deliver the number of Shares in the Redemption Basket through DTC's book-entry system to the Administrator's DTC account not later than the third Business Day following the effective date of the Redemption Basket order.

Redemption Basket Order Requirements

The Redemption Basket distribution from the Trust will consist of a transfer to the redeeming Authorized Participant of the number of the bitcoin held by the Trust in the Trust Custody Account evidenced by the Shares being delivered. Redemption distributions will be subject to the deduction of any applicable taxes or other governmental charges that may be due.

Redemption Basket Distribution

The distribution of bitcoin representing a Redemption Basket will be transferred to the Authorized Participant on the third Business Day following the Redemption Basket order date if, by 9:00 a.m. Eastern time on such third Business Day, the Administrator's DTC account has been credited with the Redemption Baskets to be redeemed. Subsequently, the Administrator will instruct the Custodian to transfer bitcoin from the Trust Custody Account and distribute it to the redeeming Authorized Participant. If the Administrator's DTC account has not been credited with all of the Shares representative of the Redemption Baskets to be redeemed by such time, the delivery will be considered unfulfilled. The Administrator is also authorized to instruct the Custodian to transfer to the Authorized Participant the distribution of bitcoin resulting from the Redemption Basket order, notwithstanding that the Redemption Baskets to be redeemed are not credited to the Administrator's DTC account by 9:00 a.m. Eastern time on the third Business Day following the Redemption Basket order date, if the Authorized Participant has collateralized its obligation to deliver the Redemption Baskets through DTC's book-entry system on such terms as the Sponsor and the Administrator may from time to time agree upon.

In order to facilitate the distribution of the bitcoin representing a Redemption Basket order, the Administrator will calculate the number of bitcoin representing the value of the Redemption Basket order and instruct the Custodian to distribute that amount of bitcoin to the redeeming Authorized Participant.

Suspension or Rejection of Redemption Basket Orders

The Administrator may, in its discretion, and will, when directed by the Sponsor, suspend the right to place Redemption Basket orders, or postpone the Redemption Basket order settlement date, (i) for any period during which BZX is closed other than customary weekend or holiday closings, or trading on BZX is suspended or restricted or (ii) for any period during which an emergency exists as a result of which the distribution or evaluation of bitcoin is not reasonably practicable or presents, in the judgment of Administrator, the Custodian, the Sponsor or their agents, a security risk to the Cold Storage System. The inability of the Custodian to operate the Cold Storage System because of a failure of hardware, software or personnel or an inability to access the Cold Storage System (*e.g.*, because of power failure or acts of God) are examples of such emergencies. None of the Administrator, the Custodian, the Sponsor or their agents will be liable to any person or in any way for any loss or damages that may result from any such suspension or postponement.

The Administrator will also reject a Redemption Basket order if the order is not in proper form as described in the Authorized Participant Agreement or if the fulfillment of the Redemption Basket order, in the opinion of its counsel, might be unlawful.

Availability of Information

The Trust's Web site, which will be publicly available prior to the public offering of the Shares, will include a form of the prospectus for the Trust that may be downloaded. The Web site will include additional quantitative information updated on a daily basis, including, for the Trust: (i) The prior Business Day's reported NAV, the highest quoted bid price for the Shares (the ''Best Bid'') and lowest quoted offer price for the Shares (the ''Best Ask''), the mid-point of the spread between the Best Bid and the Best Ask at the time of the NAV calculation (the ''Best Bid/Best Ask''),[35] the daily trading volume of the Shares, and the calculation of the premium and discount of the Best Bid/Best Ask against the NAV; and (ii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Best Bid/Best Ask against the NAV, within appropriate ranges, for each of the four (4) previous calendar quarters. Daily trading volume information for the Shares will also be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson

---

[35] The Best Bid/Best Ask of the Shares will be determined using the midpoint of the spread between the Best Bid and the Best Ask on the Exchange at the time of the NAV calculation. The records relating to Best Bid/Best Ask will be retained by the Trust and its service providers.

Reuters and International Data Corporation, which can be accessed by Authorized Participants and other investors, as well as through other electronic services, including major public Web sites.

In addition, the Sponsor will calculate an estimated fair value of the Shares based on the most recent Gemini Exchange Spot Price (the "Intraday Indicative Value"), which will be updated and widely disseminated by one or more major market data vendors at least every fifteen (15) seconds during the Exchange's regular trading hours.[36] The dissemination of the Intraday Indicative Value will provide investors with an estimate of the fair value of the Shares throughout the trading day.

Investors may obtain bitcoin pricing information twenty-four (24) hours a day or from various financial information service providers or Bitcoin Network information sites such as BitcoinCharts.com or bitcoinity.org. Bloomberg financial terminals include pricing data in USD and in Euro from several Bitcoin Exchanges. Recently, the CME and the ICE announced bitcoin pricing indices. Current Bitcoin market prices are also generally available with bid/ask spreads directly from Bitcoin Exchanges. In addition, on each Business Day, the Trust's Web site will provide pricing information for the Gemini Exchange Spot Price and the Shares. The Gemini Exchange itself provides comprehensive last trade information as well as the aggregate quantity available at each price level within its limit order book, all through its public Web site (*www.gemini.com*) and public market data feeds.

Additional information regarding the Trust and its Shares, including risks, creation and redemption procedures, fees, distributions and taxes, is included in the Registration Statement.

Arbitrage Mechanism

Similar to other ETPs listed and traded on the Exchange, the Trust will rely on the Basket creation and redemption process to reduce any premium or discount that may occur in the Share trading prices on the Exchange relative to the NAV. Baskets may be created or redeemed only by Authorized Participants who have entered into an Authorized Participant Agreement with the Trust and the Sponsor. The Basket creation and redemption process is important for the Trust in providing Authorized Participants with an arbitrage mechanism through which they may keep Share trading prices in line with the NAV. See "Overview of the Bitcoin Industry and Market—Bitcoin Value—Gemini Exchange Spot Price" above.

As the Shares trade intraday on the Exchange, their market prices will fluctuate due to supply and demand, which will be driven in large part by the price of bitcoin. The following examples generally describe the conditions surrounding Basket creation and redemption:

- If the market price of the Shares is greater than the NAV, an Authorized Participant can purchase sufficient bitcoin to create a Basket, and then sell the new Shares on the secondary market at a profit. This process increases the selling interest of the Shares and is expected to decrease the market price of the Shares such that their market price will be closer to the NAV.
- If the NAV is greater than the market price of the Shares, an Authorized Participant can purchase Shares on the secondary market in an amount equal to a Basket and redeem them for bitcoin, and then sell the bitcoin at a profit. This process increases the buying interest for the Shares and is expected to increase the market price of the Shares such that their market price will be closer to the NAV.

This process is referred to as the arbitrage mechanism ("Arbitrage Mechanism"). The Arbitrage Mechanism helps to minimize the difference between the trading price of a Share and the NAV. Over time, these buying and selling pressures should balance, and a Share's market trading price is expected to remain at a level that is at or close to the NAV. The Arbitrage Mechanism provided by the Basket creation and redemption process is designed, and required, in order to maintain the relationship between the market trading price of the Shares and the NAV. The Exchange expects that arbitrageurs will take advantage of price variations between the Shares' market price and the NAV and that the Arbitrage Mechanism will be facilitated by the transparency and simplicity of the Trust's holdings, the availability of the Intraday Indicative Value, the liquidity of the bitcoin market, each Authorized Participant's ability to access the bitcoin market, and each Authorized Participant's ability to create workable hedges.

Rule 14.11(e)(4)—Commodity-Based Trust Shares

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange will obtain a representation that the Trust's NAV will be calculated daily and that these values and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) Issued by a trust that holds a specified commodity[37] deposited with the trust; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity. The Trust currently expects that there will be at least 100,000 Shares outstanding at the time of commencement of trading on the Exchange. Upon termination of the Trust, the Shares will be removed from listing. The Trustee, Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker ("Market Maker") in the

---

[36] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available Intraday Indicative Values published via the Consolidated Tape Association ("CTA") or other data feeds.

[37] For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act. As noted above, the CFTC has opined that Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. *See* Coinflip, *supra* note 13.

Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (*see, e.g.,* Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the bitcoin underlying the Shares; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. BZX will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a) the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01 where the price is greater than $1.00 per share or $0.0001 where the price is less than $1.00 per share.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares via the Intermarket Surveillance Group ("ISG"), from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[38] In addition, the Exchange may obtain information about bitcoin transactions, trades and market data from Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement as well as certain additional information that is publicly available through the Blockchain. The Exchange notes that it has entered into a comprehensive surveillance sharing agreement with Gemini Exchange.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) The procedures for the creation and redemption of Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the Intraday Indicative Value and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares during the Pre-Opening[39] and After Hours Trading Sessions[40] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Trust is subject to various fees and expenses described in the Registration Statement. The Information Circular will also reference the fact that, apart from the CFTC, the Financial Crimes Enforcement Network of the U.S. Department of the Treasury ("FinCEN") and the US Internal Revenue Service ("IRS"), most major U.S. regulators, including the Commission, have yet to make official pronouncements or adopt rules providing guidance with respect to the classification and treatment of bitcoin and other Digital Assets for purposes of commodities, tax and securities laws. The Information Circular will also contain information regarding the CFTC's determination that bitcoin and other "virtual currencies" (aka Digital Assets) are properly defined as commodities under the CEA,[41] and will reference the fact that the CFTC has applied CEA provisions and CFTC regulations that apply to transactions in commodity options and swaps to the conduct of the bitcoin derivatives trading platform.

---

[38] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[39] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[40] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[41] *See* Coinflip, *supra* note 13.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[42] in general and Section 6(b)(5) of the Act[43] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4), which as noted above includes all statements and representations made in this filing regarding the description of the portfolio and limitations on portfolio holdings or reference assets. The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange may obtain information regarding trading in the Shares via the ISG from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[44] In addition, the Exchange may obtain information about Bitcoin transactions, trades, and market data from Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement, which includes the Gemini Exchange, as well as certain additional information that is publicly available through the Blockchain.

According to the Registration Statement, the Trust will only own and store bitcoin and will not be permitted to hold cash or any other Digital Asset. The proposal also promotes market transparency in that large amount of information is publicly available regarding the Trust and the Shares, thereby promoting market transparency. The Exchange will obtain a representation from the Sponsor that the Trust's NAV will be determined by the Administrator and published by the Sponsor at 4:00 p.m. Eastern time each Business Day (using the 4:00 p.m. Eastern time Gemini Exchange Spot Price) on the Trust's Web site and that such information will be made available to all market participants at the same time. Furthermore, the Trust's Web site will provide an Intraday Indicative Value during regular trading hours on each Business Day. The Trust's Web site will also provide its current prospectus, as well as the two (2) most recent reports to shareholders. The Web site will include additional quantitative information updated on a daily basis, including, for the Trust: (i) The prior Business Day's reported NAV, the Best Bid, the Best Ask, the Best Bid/Best Ask, the daily trading volume of the Shares, and the calculation of the premium and discount of the Best Bid/Best Ask against the NAV; and (ii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Best Bid/Best Ask against the NAV, within appropriate ranges, for each of the four (4) previous calendar quarters. In addition, the Exchange will publish (via the CTA) quotation information, trading volume, closing prices and the prior Business Day's NAV. The Intraday Indicative Value and the intraday Gemini Exchange Spot Price will be widely disseminated by one (1) or more major market data vendors, such as Reuters or Bloomberg, and broadly displayed on at least a 15-second delayed basis during regular trading hours. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the Business Day on brokers' computer screens and other electronic services, and quotation and last sale information will also be available via the Exchange's data feeds.

The proposed rule change is further designed to promote just and equitable principles of trade and to protect investors and the public interest and to promote market transparency in that there is a considerable amount of bitcoin price and market information available for free on public Web sites and through financial, professional and subscription services. Investors may obtain bitcoin pricing information twenty-four (24) hours a day or from various financial information service providers or Bitcoin Network information sites such as *www.BitcoinCharts.com* or *www.bitcoinity.org.* Bloomberg financial terminals include pricing data in USD and in Euro from several Bitcoin Exchanges. Recently, the CME and the ICE announced bitcoin pricing indices. Current Bitcoin market prices are also generally available with bid/ask spreads directly from various Bitcoin Exchanges.

The Exchange also believes that the widespread availability of information regarding bitcoin, the Trust, and the Shares, combined with the ability of Authorized Participants to create and redeem Baskets each Business Day, thereby utilizing the Arbitrage Mechanism, will be sufficient for market participants to value and trade the Shares in a manner that will not lead to significant deviations between intraday Best Bid/Best Ask and the Intraday Indicative Value as well as between the Best Bid/Best Ask and the NAV. In addition, the numerous options for buying and selling bitcoin will both provide Authorized Participants with many options for hedging their positions and provide market participants generally with potential arbitrage opportunities, further strengthening the Arbitrage Mechanism as it relates to the Shares. Furthermore, the Trust has discussed with several prominent market participants the possibility of acting as an Authorized Participant and/or a Market Maker, each of which is an experienced participant in the ETP marketplace and is actively engaged in trading ETPs. A number of these potential Authorized Participants and Market Makers currently trade bitcoin and are already registered participants that trade on the Gemini Exchange. Based on their experience in ETPs and in the Bitcoin marketplace, these market participants have indicated that they believe that they will be able to make efficient and liquid markets in the Shares at prices generally in line with the NAV.

Authorized Participants will be able to acquire bitcoin for delivery to the Trust by a variety of means. Authorized Participants will not be required to use the Gemini Exchange to trade their bitcoin and the Gemini Exchange is not the only venue on which Authorized Participants can purchase bitcoin for delivery to the Trust. However, as discussed above, the ability to transact in bitcoin on the Gemini Exchange may provide (i) a convenient and stable venue with superior liquidity characteristics in which to purchase or sell bitcoin, (ii) an efficient way to trade bitcoin, and (iii) a safe place to store purchased bitcoin for future use in the creation of Baskets given the regulatory oversight to which the Gemini Exchange is subject.

The Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (i) The extent to which trading is not occurring in the financial instruments underlying the Shares; or (ii) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

---

[42] 15 U.S.C. 78f.

[43] 15 U.S.C. 78f(b)(5).

[44] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of Commodity-Based Trust Shares that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information from other Bitcoin Exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding bitcoin pricing and bitcoin information, as well as equitable access to the Trust's Intraday Indicative Value, NAV, and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional Commodity-Based Trust Share product that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR-BatsBZX-2016-30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BatsBZX-2016-30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BatsBZX-2016-30 and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016-16604 Filed 7-13-16; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-78267; File No. SR-NYSEArca-2016-93]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 6.87 Regarding Transactions That Qualify as a Catastrophic Error as it Relates to Binary Return Derivatives Contracts

July 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act"),[2] and Rule 19b-4 thereunder,[3] notice is hereby given that on July 1, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.87 regarding transactions that qualify as a Catastrophic Error as it relates to Binary Return Derivatives contracts. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

---

[45] 17 CFR 200.30-3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 6.87 (Nullification and Adjustment of Options Transactions including Obvious Errors) regarding transactions that qualify modify [sic] a Catastrophic Error as it relates to ByRDs.

The Exchange recently amended its rules to list and trade ByRDs, and modified portions of Rule 6.87 regarding when a ByRDs transaction may qualify as a Catastrophic Error.[4] In the ByRDs filing, the Exchange clarified that any transactions in ByRDs qualifying as a Catastrophic Error "that is higher or lower than the Theoretical Price by $.50 or more shall be deemed a Catastrophic Error, subject to the adjustment procedures of paragraph (d)(3) unless such adjustment would result in a price higher than $1.02, in which case the adjustment price shall be $1.02." [5] This change was designed to ensure that ByRDs trades that are deemed Catastrophic Errors are never adjusted to a price above $1.02.

In connection with this modification, the Exchange proposes to amend Rule 6.87(d)(3)(A) to explicitly provide that any ByRDs transaction occurring at a price greater than $1.02 is presumptively a Catastrophic Error. Specifically, the current rule does not appropriately capture as Catastrophic Errors those transactions in ByRDs occurring at prices greater than $1.02 but not more than $0.50 away from the Theoretical Price.

ByRDs are binary options and, as such, differ from traditional options traded on U.S. options exchanges by providing a discontinuous or non-linear payout. An in-the-money ByRD will pay a fixed sum at expiration regardless of the magnitude of the difference between the option's exercise price and the settlement price. Specifically, at expiration, a ByRDs contract will be worth $0 or $1.00; it will never have a value greater than $1.00. Any transaction in ByRDs for over $1.00 would result in an automatic loss. Consistent with the Exchange adjusting a Catastrophic Error in a ByRDs trade to a price no greater than $1.02 as provided for in Rule 6.87(d)(3)(A), the Exchange believes that no trade in ByRDs greater than $1.02 should stand, but should instead be adjusted to $1.02.[6] Thus, the Exchange believes the proposed change would ensure that ByRDs trades that are $1.02 or more are deemed a Catastrophic Error, in addition to being appropriately adjusted.[7]

Finally, the Exchange proposes to correct the reference to "ByRDS" in Rule 6.87(d)(3)(A) to "ByRDs," which would make the reference consistent with other Exchange rules.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) [8] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the proposed change is designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, as the proposed change would ensure that ByRDs trades resulting from Catastrophic Errors are appropriately characterized as such and, in turn, appropriately adjusted. In addition, the proposed change would ensure that the Exchange would not be prevented from adjusting a trade in ByRDs that is the result of a Catastrophic Error, which would protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [11] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange stated that the proposed rule change would ensure that the manner by which the Exchange determines whether a Catastrophic Error in a ByRDs trade has occurred is consistent with the standards by which the Exchange would adjust a ByRDs trade as provided for in Rule 6.87(d)(3). The Exchange further stated that waiver of the operative delay is consistent with the protection of investors and the public interest because it would promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[13]

---

[4] *See* Securities Exchange Act Release No. 77044 (February 3, 2016), 81 FR 6908 (February 9, 2016) (SR–NYSEArca–2016–16) (the "ByRDs filing").

[5] *See* Rule 6.87(d)(3)(A). This change was made to ensure consistency with obvious errors in ByRDs, which likewise caps any adjustment to ByRDs at a price no higher than $1.02. See Rule 6.87(c)(6).

[6] *See* proposed 6.87(d)(3)(A) (providing that any transaction in ByRDs that is "(1) higher or lower than the Theoretical Price by $.50 or more or (2) at a price greater than $1.02 shall be deemed a Catastrophic Error, subject to the adjustment procedures of paragraph (d)(3) unless such adjustment would result in a price higher than $1.02, in which case the adjustment price shall be $1.02").

[7] The Exchange notes that, although ByRDs were not listed on the Exchange at the time, ByRDs contracts (which were listed on NYSE MKT) were outside of the scope of the industry wide effort to harmonize Obvious and Catastrophic Error rules, and the proposed change therefore does not impact the harmonization effort. *See* Securities Exchange Act Release No. 74920 (May 8, 2015), 80 FR 27816, 27822 (May 14, 2015) (SR–NYSEMKT–2015–39).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–93 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–93. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–93, and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16618 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78266; File No. SR–NYSEMKT–2016–66]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 975NY Regarding Transactions That Qualify as a Catastrophic Error as it Relates to Binary Return Derivatives Contracts

July 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act"),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 1, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 975NY regarding transactions that qualify as a Catastrophic Error as it relates to Binary Return Derivatives contracts ("ByRDs"). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 975NY (Nullification and Adjustment of Options Transactions including Obvious Errors) regarding transactions that qualify as a Catastrophic Error as it relates to ByRDs.

The Exchange recently amended its rules related to ByRDs, including portions of Rule 975NY regarding when a ByRDs transaction may qualify as a Catastrophic Error.[4] In the ByRDs filing, the Exchange clarified that any transactions in ByRDs qualifying as a Catastrophic Error "that is higher or lower than the Theoretical Price by $.50 or more shall be deemed a Catastrophic Error, subject to the adjustment procedures of paragraph (d)(3) unless such adjustment would result in a price higher than $1.02, in which case the adjustment price shall be $1.02."[5] This change was designed to ensure that ByRDs trades that are deemed Catastrophic Errors are never adjusted to a price above $1.02.

---

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 77014 (February 2, 2016), 81 FR 6566 (February 8, 2016) (SR–NYSEMKT–2016–16) (the "ByRDs filing").

In connection with this modification, the Exchange deleted language from the definition of Catastrophic Error providing that any ByRDs transaction occurring at a price greater than $1.02 was presumptively a Catastrophic Error.[6] The Exchange proposes to restore this concept to the rule text, as the deletion was erroneous. Specifically, the current rule does not appropriately capture as Catastrophic Errors those transactions in ByRDs occurring at prices greater than $1.02 but not more than $0.50 away from the Theoretical Price.

ByRDs are binary options and, as such, differ from traditional options traded on U.S. options exchanges by providing a discontinuous or non-linear payout. An in-the-money ByRD will pay a fixed sum at expiration regardless of the magnitude of the difference between the option's exercise price and the settlement price. Specifically, at expiration, a ByRDs contract will be worth $0 or $1.00; it will never have a value greater than $1.00. Any transaction in ByRDs for over $1.00 would result in an automatic loss. Consistent with the Exchange adjusting a Catastrophic Error in a ByRDs trade to a price no greater than $1.02 as provided for in Rule 975NY(d)(3)(A), the Exchange believes that no trade in ByRDs greater than $1.02 should stand, but should instead be adjusted to $1.02.[7] Thus, the Exchange believes the proposed change would ensure that ByRDs trades that are $1.02 or more are deemed a Catastrophic Error, in addition to being appropriately adjusted.[8]

Finally, the Exchange proposes to correct the reference to "ByRDS" in Rule 975NY(d)(3)(A) to "ByRDs," which would make the reference consistent with other Exchange rules.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)[9] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[10] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the proposed change is designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, as the proposed change would ensure that ByRDs trades resulting from Catastrophic Errors are appropriately characterized as such and, in turn, appropriately adjusted. In addition, the proposed change would ensure that the Exchange would not be prevented from adjusting a trade in ByRDs that is the result of a Catastrophic Error, which would protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[12] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange stated that the proposed rule change would ensure that the manner by which the Exchange determines whether a Catastrophic Error in a ByRDs trade has occurred is consistent with the standards by which the Exchange would adjust a ByRDs trade as provided for in Rule 975NY(d)(3). The Exchange further stated that waiver of the operative delay is consistent with the protection of investors and the public interest because it would promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

---

[5] *See* Rule 975NY(d)(3)(A). This change was made to ensure consistency with obvious errors in ByRDs, which likewise caps any adjustment to ByRDs at a price no higher than $1.02. *See* Rule 975NY(c)(6).

[6] *See supra* n. 3, 81 FR at 6566 (striking from Rule 975NY(d)(1) the caveat that "except for Binary Return Derivatives where any transaction occurring at a price greater than $1.02 shall qualify as a Catastrophic Error").

[7] *See* proposed 975NY(d)(3)(A) (providing that any transaction in ByRDs that is "(1) higher or lower than the Theoretical Price by $.50 or more or (2) at a price greater than $1.02 shall be deemed a Catastrophic Error, subject to the adjustment procedures of paragraph (d)(3) unless such adjustment would result in a price higher than $1.02, in which case the adjustment price shall be $1.02").

[8] As noted in the ByRDs filing, ByRDs contracts were outside of the scope of the industry wide effort to harmonize Obvious and Catastrophic Error rules, and the proposed change therefore does not impact the harmonization effort. *See* Securities Exchange Act Release No. 74920 (May 8, 2015), 80 FR 27816, 27822 (May 14, 2015) (SR–NYSEMKT–2015–39).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–66 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–66. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–66, and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16617 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78259; SR–NYSEArca–2015–93]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Withdrawal of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Relating to Listing and Trading of Shares of the Cumberland Municipal Bond ETF Under NYSE Arca Equities Rule 8.600

July 8, 2016.

On November 24, 2015, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Cumberland Municipal Bond ETF, a series of the ETFis Series Trust I. The proposed rule change was published for comment in the **Federal Register** on December 14, 2015.[3] On December 29, 2015, the Exchange submitted Amendment No. 1 to the proposed rule change.[4] On January 21, 2016, pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On March 10, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1 thereto.[8] On June 7, 2016, the Commission issued a notice of designation of a longer period for Commission action on proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1 thereto.[9] The Commission received no comments on the proposed rule change.

On June 29, 2016, the Exchange withdrew the proposed rule change (SR–NYSEArca–2015–93).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16601 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76590 (Dec. 8, 2015), 80 FR 77384 ("Notice").

[4] In Amendment No. 1, the Exchange clarified that each Municipal Bond (as defined herein) held by the Fund must be a constituent of a deal where the deal's original offering amount was at least $100 million, clarified whether certain securities would be exchange-traded or over-the-counter, deleted a statement relating to redemption of Shares, clarified pricing information for certain assets, and corrected a typographical error. Amendment No. 1, which amended and replaced the original proposal in its entirety, is available on the Commission's Web site at: *http://www.sec.gov/comments/sr-nysearca-2015-93/nysearca201593-1.pdf*.

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 76955, 81 FR 4724 (Jan. 27, 2016). *See also* Securities Exchange Act Release No. 76955A (Mar. 2, 2016), 81 FR 12174 (Mar. 8, 2016) (correcting the date to "March 11, 2016" as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 77340, 81 FR 14163 (Mar. 16, 2016).

[9] *See* Securities Exchange Act Release No. 78003, 81 FR 38258 (Jun. 13, 2016).

[10] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78261; SR–NYSEArca–2016–08]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Withdrawal of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Adopt NYSE Arca Equities Rule 8.900 To Permit Listing and Trading of Managed Portfolio Shares and To Permit Listing and Trading of Shares of Fifteen Issues of the Precidian ETFs Trust

July 8, 2016.

On January 27, 2016, NYSE Arca, Inc. ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to: (1) Adopt NYSE Arca Equities Rule 8.900; and (2) approve the listing and trading of shares of fifteen series of the Precidian ETFs Trust. The proposed rule change was published for comment in the **Federal Register** on February 18, 2016.[3] On March 9, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.[4]

---

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76944 (Feb. 11, 2016), 81 FR 8269 ("Notice").

On March 18, 2016, pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On May 17, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change.[8] The Commission received eleven comments on the proposal.[9]

On July 7, 2016, the Exchange withdrew the proposed rule change (SR–NYSEArca–2016–08).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16603 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[4] In Amendment No. 1 to the proposed rule change, the Exchange corrected the citations to the Trust's Form N–1A and Exemptive Application, which were misstated in the proposal. Amendment No. 1 to the proposed rule change is available on the Commission's Web site at: *http://www.sec.gov/comments/sr-nysearca-2016-08/nysearca201608-1.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 77405, 81 FR 15774 (Mar. 24, 2016).

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 77845, 81 FR 32376 (May 23, 2016).

[9] *See* Letters from Douglas M. Yones, Head of Exchange Traded Products, New York Stock Exchange (Jul. 5, 2016); Eric Swanson, General Counsel & Secretary, Bats Global Markets, Inc. (Jul. 1, 2016); Todd J. Broms, CEO, Broms and Company LLC (Jun. 27, 2016); Daniel J. McCabe, CEO, Precidian Investments LLC (Jun. 15, 2016); Gary L. Gastineau, President, ETF Consultants.com, Inc. (Jun. 13, 2016); Daniel J. McCabe, CEO, Precidian Investments LLC (Jun. 13, 2016); James J. Angel, Ph.D., CFA, Associate Professor, McDonough School of Business, Georgetown University (Jun. 9, 2016); Joseph A. Sullivan, Chairman and Chief Executive Officer, Legg Mason Global Asset Management (Apr. 15, 2016); Andrew M. Gross, Jr. (Apr. 5, 2016); David Nadig (Mar. 31, 2016); and Gary L. Gastineau, President, ETF Consultants.com, Inc. (Mar. 10, 2016) (comment letters available at: *https://www.sec.gov/comments/sr-nysearca-2016-08/nysearca201608.shtml*).

[10] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78265; File No. SR–MIAX–2016–19]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 515A To Extend the MIAX Price Improvement Mechanism ("PRIME") Auction Pilot Program Until January 18, 2017

July 8, 2016.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 7, 2016, Miami International Securities Exchange LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 515A, Interpretations and Policies .08 to extend certain aspects of the MIAX Price Improvement Mechanism ("PRIME") Auction pilot program ("Pilot Program").

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing*, at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot period applicable to certain aspects of the Pilot Program which is currently set to expire on July 18, 2016,[3] until January 18, 2017.

The current pilot allows PRIME Agency Orders of any size to initiate a PRIME Auction on MIAX at a price which is at or better than the national best bid or offer ("NBBO").[4] The Exchange implemented the pilot in order to benefit customers through the encouragement of the entry of more orders into the PRIME Auction, thus making it more likely that such orders may receive price improvement. The Exchange believes that the Pilot Program attracts order flow and promotes competition and price improvement opportunities for Agency Orders of fewer than 50 contracts. The Exchange believes that extending the Pilot Program period is appropriate because it would allow the Exchange and the Commission additional time to analyze data regarding the pilot that the Exchange has committed to provide.

In its filing to adopt the MIAX PRIME Price Improvement Mechanism in 2014 the Exchange committed to submit reports periodically based on the comprehensive list of data the Exchange represented it would collect in order to aid the Commission in its evaluation of the PRIME mechanism.[5] In November 2014 the Exchange established a Pilot Program to allow orders of less than 50 contracts or 500 mini-option contracts to initiate a PRIME Auction,[6] and began submitting revised periodic reports on August 1, 2015, based on the revised list of data detailed in Exhibit 3 of the Exchange's filing to extend the Pilot Program an additional year to July 18, 2016.[7] Any raw data which is submitted to the Commission pursuant to the Pilot Program will be provided on a confidential basis. The Exchange continues to believe that there remains meaningful competition for all size orders and that there is an active and liquid market functioning on the Exchange outside of the PRIME Auction. The Exchange also continues to believe that there are significant opportunities for price improvement available in the PRIME Auction.

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release Nos. 73590 (November 13, 2014), 79 FR 68919 (SR–MIAX–2014–56) (establishing the PRIME Pilot Program) and 75486 (July 20, 2015), 80 FR 44174 (July 24, 2015) (SR–MIAX–2015–48) (extending certain aspects of the PRIME Pilot Program to July 18, 2016).

[4] The Exchange notes that prior to the pilot, for PRIME Agency Orders for less than 50 standard option contracts or 500 mini-option contracts, the Initiating Member must stop the entire PRIME Agency Order as principal or with a solicited order at the better of the NBBO price improved by a $0.01 increment or the PRIME Agency Order's limit price (if the order is a limit order). In addition, to initiate the PRIME Auction for auto-match submissions, the Initiating Member must stop the PRIME Agency Order for less than 50 standard option contracts or 500 mini-option contracts at the better of the NBBO price improved by a $0.01 increment or the PRIME Agency Order's limit price. *See* Securities Exchange Act Release No. 73590 (November 13, 2014), 79 FR 68919 (November 19, 2014) (SR–MIAX–2014–56).

[5] *See* Securities Exchange Act Release No. 72009 (April 23, 2014) 79 FR 24032 (April 29, 2014) (SR–MIAX–2014–09) (Order approving adoption of the MIAX PRIME Price Improvement Mechanism).

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act[8] in general, and furthers the objectives of Section 6(b)(5) of the Act[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that extending the Pilot Program is consistent with these principles because the Pilot Program is reasonably designed to create tighter markets and ensure that each order receives the best possible price, which benefits investors by increasing competition thereby maximizing opportunities for price improvement. The proposed extension would allow the pilot to continue uninterrupted, thereby avoiding any potential investor confusion that could result from a temporary interruption in the pilot. Because the Pilot Program is applicable to all PRIME Agency Orders for fewer than 50 contracts, the proposal to extend the Pilot Program merely acts to maintain the status quo on the Exchange, which promotes just and equitable principles of trade and removes impediments to, and perfects the mechanism of, a free and open market and a national market system.

The extension of the Pilot Program period will allow the Commission and the Exchange to continue to monitor the Pilot Program to ascertain whether there is meaningful competition for all size orders and whether there is an active and liquid market functioning on the Exchange outside of the PRIME Auction. The extension of the Pilot Program period would also enable market participants to continue to benefit from the significant opportunities for price improvement available in the PRIME Auction.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change simply extends an established pilot program for an additional period and would allow for further analysis of the pilot. In addition, the proposed extension would allow the Pilot Program to continue uninterrupted, thereby avoiding any potential investor confusion that could result from a temporary interruption in the Pilot Program. Thus, the proposal would also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6)[12] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay. The Exchange noted that waiver of the 30-day operative delay would allow for the Pilot Program to continue uninterrupted.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Pilot Program to continue uninterrupted, thereby avoiding any potential investor confusion that could result from a temporary interruption in the Pilot Program. Therefore, the Commission designates the proposed rule change to be operative on July 18, 2016.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email *to rule-comments@sec.gov.* Please include File Number SR–MIAX–2016–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

---

[6] *See* Securities Exchange Act Release No. 68919 [sic] (November 13, 2014), 79 FR 68919 (November 19, 2014) (SR–MIAX–2014–56) (establishing the PRIME Pilot Program).

[7] *See* Securities Exchange Act Release No. 75486 (July 20, 2015), 80 FR 44174 (July 24, 2015) (SR–MIAX–2015–48) (extending certain aspects of the PRIME Pilot Program to July 18, 2016).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

All submissions should refer to File Number SR–MIAX–2016–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2016–19 and should be submitted on orbefore August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16616 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78263; File No. SR–NYSE–2016–44]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Allowing the Exchange To Trade Pursuant to Unlisted Trading Privileges for Any NMS Stock Listed on Another National Securities Exchange; Establishing Listing and Trading Requirements for Exchange Traded Products; and Adopting New Equity Trading Rules Relating to Trading Halts of Securities Traded Pursuant to UTP on the Pillar Platform

July 8, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on June 30, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) allow the Exchange to trade pursuant to unlisted trading privileges ("UTP") for any NMS Stock[4] listed on another national securities exchange; (2) establish listing and trading requirements for exchange traded products ("ETPs"); and (3) adopt new equity trading rules relating to trading halts of securities traded pursuant to UTP on the Pillar platform. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing new rules to trade all Tape B and Tape C symbols, on a UTP basis, on its new trading platform, Pillar.[5] The Exchange does not currently trade any securities on a UTP basis.

In addition, the Exchange is proposing rules for the listing and trading of the following types of Exchange Traded Products:[6]

- Equity Linked Notes ("ELNs");
- Investment Company Units;
- Index-Linked Exchangeable Notes;
- Equity Gold Shares;
- Equity Index-Linked Securities;
- Commodity-Linked Securities;
- Currency-Linked Securities;
- Fixed-Income Index-Linked Securities;
- Futures-Linked Securities;
- Multifactor-Index-Linked Securities;
- Trust Certificates;
- Currency and Index Warrants;
- Portfolio Depositary Receipts;
- Trust Issued Receipts;
- Commodity-Based Trust Shares;
- Currency Trust Shares;
- Commodity Index Trust Shares;
- Commodity Futures Trust Shares;
- Partnership Units;
- Paired Trust Shares;
- Trust Units;
- Managed Fund Shares; and
- Managed Trust Securities.

The Exchange's proposed rules for these products are substantially identical (other than with respects[sic] to certain non-substantive and technical amendments described below) as the rules of NYSE Arca Equities for the qualification, listing and trading of such products.[7]

---

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] NMS Stock is defined in Rule 600 of Regulation NMS, 17 CFR 242.600(b)(47).

[5] On January 29, 2015, the Exchange announced the implementation of Pillar, which is an integrated trading technology platform designed to use a single specification for connecting to the equities and options markets operated by the Exchange and its affiliates, NYSE Arca, Inc. ("NYSE Arca") and NYSE MKT LLC ("NYSE MKT"). *See* Trader Update dated January 29, 2015, available here: *http://www1.nyse.com/pdfs/Pillar_Trader_Update_Jan_2015.pdf.*

[6] The Exchange is proposing to define the term "Exchange Traded Product" to mean a security that meets the definition of "derivative securities product" in Rule 19b–4(e) under the Securities Exchange Act of 1934. *See* proposed Rule 1.1(bbb). This proposed definition is identical to the definition of "Derivatives Securities Product" in NYSE Arca Equities Rule 1.1(bbb).

The Exchange's approach in this filing is the same as the approach of (1) BATS BYX Exchange, Inc. f/k/a BATS Y-Exchange, Inc. ("BYX"), which filed a proposed rule change with the Commission to conform its rules to the rules of its affiliate, Bats BZX Exchange, Inc. f/k/a BATS Exchange, Inc. ("BATS"),[8] (2) NASDAQ Stock Market LLC, which filed a proposed rule change with the Commission to amend its rules regarding Portfolio Depository Receipts and Index Fund Shares to conform to the rules of NYSE Arca,[9] and (3) American Stock Exchange LLC ("Amex"), which filed a proposed rule change with the Commission to copy all of the relevant rules of Amex in their entirety (other than with respects[sic] to certain non-substantive and technical changes) for adoption by its new trading platform for equity products and exchange traded funds—AEMI.[10]

The Exchange's only trading pursuant to UTP will be on the Pillar platform; it will not trade securities pursuant to UTP on its current platform. Further, at this time, the Exchange does not intend to list ETPs on its Pillar platform and will only trade ETPs on the Pillar platform pursuant to UTP. Therefore, the Exchange is only proposing ETP rules in this rule filing that would apply to the Pillar platform, and the Exchange is not proposing to change any of the current rules of the Exchange pertaining to the listing and trading of ETPs in the NYSE Listed Company Manual[11] or in its other rules.

In accordance with the rule numbering framework adopted by the Exchange in the Pillar Framework Filing,[12] each rule proposed herein would have the same rule numbers as the NYSE Arca Equities rules with which it conforms.

Finally, in the Pillar Framework Filing, the Exchange adopted rules grouped under proposed Rule 7P relating to equities trading.[13] The Exchange now proposes Rule 7.18 under Rule 7P relating to trading halts of securities traded pursuant to UTP on the Pillar platform. The Exchange's proposed Rule 7.18 is substantially identical (other than with respects[sic] to certain non-substantive and technical amendments described below) as NYSE Arca Equities Rule 7.18P.[14]

Proposal To Trade Securities Pursuant to UTP

The Exchange is proposing new Rule 5.1(a) to establish rules regarding the extension of UTP securities listed on other national securities exchanges. The Exchange currently only trades securities for which it is the listing exchange and that qualify under the requirements for listing set forth in its Listed Company Manual. As proposed, the first sentence of new Rule 5.1(a) would allow the Exchange to trade securities eligible for UTP under Section 12(f) of the Exchange Act.[15] This proposed text is identical to Rules 14.1 of both BYX and EDGA Exchange, Inc. ("EDGA").

Proposed Rule 5.1(a) would adopt rules reflecting requirements for trading products on the Exchange pursuant to UTP that have been established in various new product proposals previously approved by the Commission.[16] In addition, proposed Rule 5.1(a) would state that the securities the Exchange trades pursuant to UTP would be traded on the new Pillar trading platform under the rules applicable to such trading.[17] Accordingly, the Exchange would not trade UTP securities until its trading rules for the Pillar platform are effective.

Finally, proposed Rule 5.1(a)(1) would make clear that the Exchange would not list any ETPs, unless it filed a proposed rule change under Section 19(b)(2)[18] under the Act. Therefore, the provisions of proposed Rules 5P and 8P described below, which permit the listing of ETPs, would not be effective until the Exchange files a proposed rule change to amend its rules to comply with Rules 10A–3 and 10C–1 under the Act and to incorporate qualitative listing criteria, and such proposed rule change is approved by the Commission. This would require the Exchange to adopt rules relating to the independence of compensation committees and their advisors.[19]

UTP of Exchange Traded Products

The Exchange proposes Rule 5.1(a)(2) to specifically govern trading of ETPs pursuant to UTP. Specifically, the requirements in subparagraphs (A)–(F) of proposed Rule 5.1(a)(2) would apply to ETPs traded pursuant to UTP on the Exchange.

Under proposed Rule 5.1(a)(2)(A), the Exchange would file a Form 19b–4(e) with the Commission with respect to each ETP[20] the Exchange trades

---

[7] *See* NYSE Arca Equities Rules 5 (Listings) and 8 (Trading of Certain Equities Derivatives).

[8] *See*, Securities Exchange Act Release No. 63097 (October 13, 2010), 75 FR 64767 (October 20, 2010) (SR–BYX–2010–002).

[9] *See*, Securities Exchange Act Release No. 69928 (July 3, 2013), 78 FR 41489 (July 10, 2013) (SR–NASDAQ–2013–094).

[10] *See*, Securities Exchange Act Release No. 54552 (September 29, 2006), 71 FR 59546 (October 10, 2006) (SR–Amex–2005–104) and Securities Exchange Act Release No. 54145 (July 14, 2006), 71 FR 41654 (July 21, 2006) (SR–Amex–2005–104).

[11] NYSE Listed Company Manual, *http://nysemanual.nyse.com/LCM/Sections/*.

[12] *See*, Securities Exchange Act Release No. 76803 (December 30, 2015), 81 FR 536 (January 6, 2016) (SR–NYSE–2015–67) ("Pillar Framework Filing"). The Exchange is using the same rule numbering framework as the NYSE Arca Equities rules and would consist of proposed Rules 1P–13P. Rules 1P–13P would be operative for securities that are trading on the Pillar trading platform.

[13] The Pillar Framework Filing added Rules 7.5 and 7.6 for trading on the Pillar platform. Since trading on the Pillar platform will be under these new rules, the Exchange specified in the Pillar Framework Filing that current Exchange Rule 7 would not be applicable to trading on the Pillar trading platform. In addition, the Exchange added Rules 7.1–Rule 7.44 on a "Reserved" basis, grouped under Rule 7P relating to equities trading on the Pillar platform. *Id.*

[14] *See*, NYSE Arca Equities Rule 7.18P. *See, also*, Securities Exchange Act Release No. 75467 (July 16, 2015), 80 FR 43515 (July 22, 2015) (SR–NYSEArca–2015–58), as amended by Amendment No. 1; Securities Exchange Act Release No. 76198A[sic] (October 20, 2015), 80 FR 65274 (October 26, 2015) (SR–NYSEArca–2015–58).

[15] Section 12(f) of the Exchange Act. 15 U.S.C. 78l(f).

[16] *See*, NYSE Arca Equities Rule 5.1(a)(1) and Securities Exchange Act Release No. 67066 (May 29, 2012), 77 FR 33010 (June 4, 2012) (SR–NYSEArca–2012–46); BATS Rule 14.11 and Securities Exchange Act Release No. 58623 (September 23, 2008), 73 FR 57169 (October 1, 2008) (SR–BATS–2008–004); National Stock Exchange, Inc. ("NSX") Rule 15.9 and Securities Exchange Act Release No. 57448 (March 6, 2008), 73 FR 13597 (March 13, 2008) (SR–NSX–2008–05); NASDAQ OMX PHLX LLC ("Phlx") Phlx Rule 803(o) and Securities Exchange Act Release No. 57806 (May 9, 2008), 73 FR 28541 (May 16, 2008) (SR–Phlx2008–34); International Securities Exchange, LLC ("ISE") ISE Rule 2101 and Securities Exchange Act Release No. 57387 (February 27, 2008), 73 FR 11965 (March 5, 2008) (SR–ISE–2007–99).

[17] *See*, Securities Exchange Act Release No. 76803 (December 30, 2015), 81 FR 536 (January 6, 2016) (SR–NYSE–2015–67). In this filing, the Exchange established the same rule numbering framework as the NYSE Arca Equities rules and would consist of proposed Rules 1P–13P. The Exchange explained in this filing that Rules 1P–13P would be operative for securities that are trading on the Pillar trading platform.

[18] 15 U.S.C. 78s(b)(2).

[19] On June 20, 2012, the Commission adopted Rule 10C–1 to implement Section 10C of the Act, as added by Section 952 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Rule 10C–1 under the Act directs each national securities exchange to prohibit the listing of any equity security of an issuer, with certain exceptions, that does not comply with the rule's requirements regarding compensation committees of listed issuers and related requirements regarding compensation advisers. *See*, CFR 240.10C–1; Securities Act Release No. 9199, Securities Exchange Act Release No. 64149 (March 30, 2011), 76 FR 18966 (April 6, 2011) and Securities Exchange Act Release No. 67220 (June 20, 2012), 77 FR 38422 (June 27, 2012).

[20] Although Rule 19b–4(e) of the Act defines any type of option, warrant, hybrid securities product or any other security, other than a single equity option or a security futures product, whose value

Continued

pursuant to UTP within five days after commencement of trading.

The Exchange proposes Supplementary Material .01 to Rule 5.1(a) to allow the Exchange to trade, pursuant to UTP, any ETP that (1) was originally listed on another registered national securities exchange ("Other SRO") and continues to be listed on such Other SRO; and (2) satisfies the Exchange's continued listing criteria that are applicable to the product class that would include such ETP. For the purposes of Supplementary Material .01 to proposed Rule 5.1(a), the term "Exchange Traded Product" would include securities described in proposed Rules 5.2(j)(2) (Equity Linked Notes); 5.2(j)(3) (Investment Company Units); 5.2(j)(4) (Index-Linked Exchangeable Notes); 5.2(j)(6) (Equity Index-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Fixed Income Index-Linked Securities, Futures-Linked Securities and Multifactor Index-Linked Securities); 8.100 (Portfolio Depositary Receipts); and Supplementary Material .01 to Rule 8.200 (Trust Issued Receipts).

In addition, proposed Rule 5.1(a)(2)(B) would provide that the Exchange will distribute an information circular prior to the commencement of trading in such an ETP that generally would include the same information as the information circular provided by the listing exchange, including (a) the special risks of trading the ETP, (b) the Exchange's rules that will apply to the ETP, including Rules 2090 and 2111,[21] and (c) information about the dissemination of value of the underlying assets or indices.

Under proposed Rule 5.1(a)(2)(D), the Exchange would halt trading in a UTP Exchange Traded Product in certain circumstances. Specifically, if a temporary interruption occurs in the calculation or wide dissemination of the intraday indicative value (or similar value) or the value of the underlying index or instrument and the listing market halts trading in the product, the Exchange, upon notification by the listing market of such halt due to such temporary interruption, also would immediately halt trading in that product on the Exchange. If the intraday indicative value (or similar value) or the value of the underlying index or instrument continues not to be calculated or widely available as of the commencement of trading on the Exchange on the next business day, the Exchange would not commence trading of the product that day. If an interruption in the calculation or wide dissemination of the intraday indicative value (or similar value) or the value of the underlying index or instrument continues, the Exchange could resume trading in the product only if calculation and wide dissemination of the intraday indicative value (or similar value) or the value of the underlying index or instrument resumes or trading in such series resumes in the listing market. The Exchange also would halt trading in a UTP Exchange Traded Product listed on the Exchange for which a net asset value (and in the case of managed fund shares or actively managed exchange-traded funds, a "disclosed portfolio") is disseminated if the Exchange became aware that the net asset value or, if applicable, the disclosed portfolio was not being disseminated to all market participants at the same time. The Exchange would maintain the trading halt until such time as the Exchange became aware that the net asset value and, if applicable, the disclosed portfolio was available to all market participants.

Finally, the Exchange represents that its surveillance procedures for ETPs traded on the Exchange pursuant to UTP would be similar to the procedures used for equity securities traded on the Exchange and would incorporate and rely upon existing Exchange surveillance systems.

Proposed Rules 5.1(a)(2)(C) and (E) would establish the following requirements for member organizations that have customers that trade UTP Exchange Traded Products:

- *Prospectus Delivery Requirements.* Proposed Rule 5.1(a)(2)(C)(i) would remind member organizations that they are subject to the prospectus delivery requirements under the Securities Act of 1933, as amended (the "Securities Act"), unless the ETP is the subject of an order by the Commission exempting the product from certain prospectus delivery requirements under Section 24(d) of the Investment Company Act of 1940, as amended (the "1940 Act"), and the product is not otherwise subject to prospectus delivery requirements under the Securities Act. Member organizations would also be required to provide a prospectus to a customer requesting a prospectus.[22]
- *Written Description of Terms and Conditions.* Proposed Rule 5.1(a)(2)(C)(ii) would require member organizations to provide a written description of the terms and characteristics of UTP Exchange Traded Products to purchasers of such securities, not later than the time of confirmation of the first transaction, and with any sales materials relating to UTP Exchange Traded Products.
- *Market Maker Restrictions.* Proposed Rule 5.1(a)(E) would establish certain restrictions for any member organization registered as a market maker in an ETP that derives its value from one or more currencies, commodities, or derivatives based on one or more currencies or commodities, or is based on a basket or index composed of currencies or commodities (collectively, "Reference Assets"). Specifically, such a member organization must file with the Exchange and keep current a list identifying all accounts for trading the underlying physical asset or commodity, related futures or options on futures, or any other related derivatives, which the member organization acting as registered market maker may have or over which it may exercise investment discretion.[23] If an account in which a member organization acting as a registered market maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, has not been reported to the Exchange as required by this Rule, a member organization acting as registered market maker in the ETP would be permitted to trade in the underlying physical asset or commodity, related futures or options on futures, or any other related derivatives. Finally, a market maker could not use any material nonpublic information in connection with trading a related instrument.

Proposed Requirements for Exchange Traded Products

Definitions & Terms of Use

The Exchange proposes to define the term "exchange traded product" in Rule

---

is based, in whole or in part, upon the performance of, or interest in, an underlying instrument, as a "new derivative securities product," the Exchange prefers to refer to these types of products that it will be trading as "exchange traded products," so as not to confuse investors with a term that can be deemed to imply such products are futures or options related.

[21] *See,* Rule 2090 (the Exchange's Know Your Customer Rule) and Rule 2111 (the Exchange's Suitability Rule). *See, also,* SR–NYSE–2016–33.

[22] Proposed Rule 5.1(a)(2)(C)(iii).

[23] The proposed rule would also, more specifically, require a market maker to file with the Exchange and keep current a list identifying any accounts ("Related Instrument Trading Accounts") for which related instruments are traded (1) in which the market maker holds an interest, (2) over which it has investment discretion, or (3) in which it shares in the profits and/or losses. In addition, a market maker would not be permitted to have an interest in, exercise investment discretion over, or share in the profits and/or losses of a Related Instrument Trading Account that has not been reported to the Exchange as required by the proposed rule.

1.1(bbb). Proposed Rule 1.1(bbb) would define the term "Exchange Traded Product" to mean a security that meets the definition of "derivative securities product" in Rule 19b–4(e) under the Securities Exchange Act of 1934 and a "UTP Exchange Traded Product" to mean an Exchange Traded Product that trades on the Exchange pursuant to unlisted trading privileges.[24] The Exchange proposes to use the term Exchange Traded Product instead of "derivative securities product," because it believes that the term "Exchange Traded Product" more accurately describes the types of products the Exchange proposes to trade and is less likely to confuse investors by using a term that implies such products are futures or options related.

Next, the Exchange proposes to add the definitions contained in NYSE Arca Equities Rule 5.1(b) that are relevant to the ETP listing and trading rules the Exchange proposes in this filing, which are described below. To maintain consistency in rule references between the Exchange's proposed rules and NYSE Arca Equities' rules, the Exchange proposes to Reserve subparagraphs to the extent it is not now proposing certain definitions from NYSE Arca Equities Rule 5.1(b).[25] Other than a non-substantive difference to use the term "Exchange" instead of "Corporation," "NYSE Arca Marketplace," or "NYSE Arca Parent," the terms defined in this proposed Rule 5.1(b) would have the identical meanings to the terms used in NYSE Arca Equities Rule 5.1(b).

Finally, the Exchange proposes to make the following substitutions in its proposed rules for terms used in the NYSE Arca Equities ETP listing and trading rules (collectively, the "General Definitional Term Changes"):

- Because the Exchange uses the term "Supplementary Material" to refer to commentaries to its Rules, the Exchange proposes to substitute this term where "Commentary" is used in the rules of NYSE Arca Equities;
- Because the Exchange tends to use the term "will" to impose obligations or duties on its members and member organizations, the Exchange proposes to substitute this term where "shall" is used in the rules of NYSE Arca Equities;
- Because members of the Exchange, as defined in Rule 2, are referred to as "member organizations" under the Exchange's rules, the Exchange proposes to substitute this term where "ETP Holder"[26] is used in the rules of NYSE Arca Equities;
- The Exchange proposes to use the term "Exchange"[27] instead of "Corporation," "NYSE Arca Marketplace," or "NYSE Arca Parent;"
- The Exchange is proposing to substitute in its proposed rules the phrase "member organization registered as a market maker on the Exchange" for the term "Market Maker,"[28] as defined in the rules of NYSE Arca Equities;
- Because the Exchange's hours for business are described in Rule 51 and the Exchange's rules do not use a defined term to refer to such hours, the Exchange is proposing to refer to its core trading hours as the "Exchange's normal trading hours," and substitute this phrase for "Core Trading Session" and "Core Trading Hours," as defined in the rules of NYSE Arca Equities;
- Because the Exchange's rules pertaining to trading halts due to extraordinary market volatility are described in Rule 80B, the Exchange is proposing to refer to Rule 80B in its proposed rules wherever NYSE Arca Equities Rule 7.12[29] is referenced in the rules of NYSE Arca Equities proposed in this filing;
- Because the Exchange's rules pertaining to the mechanics of the limit-up-limit down plan as it relates to trading pauses in individual securities due to extraordinary market volatility are described in Rule 80C, the Exchange is proposing to refer to Rule 80C in its proposed rules wherever NYSE Arca Equities Rule 7.11P[30] is referenced in the rules of NYSE Arca Equities proposed in this filing; and
- Because NYSE Arca Equities Rule 7.18P[31] establishes the requirements for trading halts in securities traded on the Pillar trading platform, and the Exchange is proposing new Rule 7.18 in this filing, based on NYSE Arca Equities Rule 7.18P, the Exchange is proposing to refer to Rule 7.18 in its proposed rules wherever NYSE Arca Equities Rule 7.34 is referenced in the rules of NYSE Arca Equities proposed in this filing.

Listing and Trading Requirements for ETPs

If an exchange has approved trading rules, procedures and listing standards in place that have been approved by the Commission for the product class that would include a new derivative securities product, the listing and trading of such "new derivative securities product," does not require a proposed rule change under Section 19b–4 of the Act. The Exchange would, however, have to file a Form 19b–4(e) with the Commission to trade these ETPs. For this purpose, the Exchange is proposing substantially identical rules to those of NYSE Arca Equities for the qualification, listing and delisting of companies on the Exchange applicable to the ETPs.[32]

Proposed Rule 5P—Securities Traded

The Exchange proposes to add Rules 5.2(j)(2)–(j)(7), which would be substantially identical to NYSE Arca Equities Rules 5.2(j)(2)–(j)(7). These proposed rules would permit the Exchange to trade pursuant to UTP the following:

- Equity Linked Notes that meet the listing and trading requirements in proposed Rule 5.2(j)(2);
- Investment Company Units that meet the listing and trading requirements in proposed Rule 5.2(j)(3);
- Index-Linked Exchangeable Notes that meet the listing and trading requirements in proposed Rule 5.2(j)(4);
- Equity Gold Shares that meet the listing and trading requirements in proposed Rule 5.2(j)(5);
- Equity Index Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Fixed Income Index-Linked Securities, Futures-Linked Securities, and Multifactor Index-Linked Securities that meet the listing and trading requirements in proposed Rule 5.2(j)(6); and

---

[24] This proposed definition is identical to the definition of "Derivative Securities Product" in NYSE Arca Equities Rule 1.1(bbb).

[25] The Exchange is proposing to Reserve paragraphs (b)(3), (b)(7), (b)(8), (b)(10), (b)(17) and (b)(19) of proposed Rule 5.1(b), because the terms used in the parallel provisions of the NYSE Arca Equities rules would not be used in the listing and trading requirements for ETPs that the Exchange is proposing in this filing.

[26] The term "member," when used with respect to a national securities exchange, is defined in Section 3(a)(3)(A) of the Act to mean any registered broker or dealer with which such a natural person is associated. NYSE Arca Equities Rule 1.1(m) defines "ETP" as an Equity Trading Permit issued by the Corporation for effecting approved securities transactions on the Corporation's Trading Facilities. *See, also,* NYSE Arca Equities Rule 1.1(n).

[27] Under Rule 1, the term "the Exchange," when used with reference to the administration of any rule, means the New York Stock Exchange LLC or the officer, employee, person, entity or committee to whom appropriate authority to administer such rule has been delegated by the Exchange.

[28] NYSE Arca Equities Rule 1.1(v) defines "Market Maker" as an ETP Holder that acts as a market maker pursuant to NYSE Arca Equities Rule 7 (Equities Trading).

[29] Exchange Rule 80B is substantially identical to NYSE Arca Equities Rule 7.12, which pertains to Trading Halts Due to Extraordinary Market Volatility.

[30] Exchange Rule 80C is substantially identical to NYSE Arca Equities Rule 7.11P, which pertains to the Limit Up-Limit Down Plan and Trading Pauses In Individual Securities Due to Extraordinary Market Volatility.

[31] *See* supra note 14.

[32] Each proposed NYSE Rule corresponds to the same rule number as the NYSE Arca Equities rules with which it conforms.

- Trust Certificates that meet the listing and trading requirements in proposed Rule 5.2(j)(7).

The text of these proposed rules is identical to NYSE Arca Equities Rules 5.2(j)(2)–5.2(j)(7), other than certain non-substantive and technical differences explained below.

The Exchange proposes to Reserve paragraphs 5.2(a)–(i) [33] and (j)(1),[34] to maintain the same rule numbers as the NYSE Arca rules with which it conforms.

Proposed Rule 5.2(j)(2)—Equity Linked Notes ("ELNs")

The Exchange is proposing Rule 5.2(j)(2) to provide listing and trading requirements for ELNs, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 5.2(j)(2).[35]

Proposed Rule 5.2(j)(3)—Investment Company Units

The Exchange is proposing Rule 5.2(j)(3) to provide listing and trading requirements for investment company units, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 5.2(j)(3).[36]

Proposed Rule 5.2(j)(4)—Index-Linked Exchangeable Notes

The Exchange is proposing Rule 5.2(j)(4) to provide listing and trading requirements for index-linked exchangeable notes, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive changes between this proposed rule and NYSE Arca Equities Rule 5.2(j)(4): [37]

- To qualify for listing and trading under NYSE Arca Equities Rule 5.2(j)(4), an index-linked exchangeable note and its issuer must meet the criteria in NYSE Arca Equities Rule 5.2(j)(1) (Other Securities), except that the minimum public distribution will be 150,000 notes with a minimum of 400 public note-holders, except, if traded in thousand dollar denominations then there is no minimum public distribution and number of holders.

Because the Exchange does not have and is not proposing a rule for "Other Securities" comparable to NYSE Arca Rule 5.2(j)(1), the Exchange proposes to reference NYSE Arca Equities Rule 5.1(j)(1) in subparagraphs (a) and (c) of proposed Rule 5.2(j)(4) in establishing the criteria that an issuer and issue must satisfy.[38]

- To qualify for listing and trading under NYSE Arca Equities Rule 5.2(j)(4), an index to which an exchangeable note is linked and its underlying securities must meet (i) the procedures in NYSE Arca Options Rules 5.13(b)–(c); or (ii) the criteria set forth in subsections (C) and (D) of NYSE Arca Equities Rule 5.2(j)(2), the index concentration limits set forth in NYSE Arca Options Rule 5.13(b)(6), and Rule 5.13(b)(12) insofar as it relates to Rule 5.13(b)(6).[39] Because the Exchange does not have and is not proposing a rule for listing of index option contracts comparable to NYSE Arca Options Rule 5.13, the Exchange proposes to reference NYSE Arca Options Rule 5.13 in paragraph (d) of proposed Rule 5.2(j)(4).[40] The Exchange would apply the criteria set forth in NYSE Arca Options Rule 5.13 in determining whether an index underlying an index-linked exchangeable note satisfies the requirements of Rule 5.2(j)(4)(d).
- Correction of a typographical error in NYSE Arca Equities Rule 5.2(j)(4)(f)((iii), so that proposed Rule 5.2(j)(4)(f)((iii) reads "further dealings on the Exchange," rather than "further dealings of the Exchange," as is currently drafted in NYSE Arca Equities Rule 5.2(j)(4)(f)(iii).

Proposed Rule 5.2(j)(5)—Equity Gold Shares

The Exchange is proposing Rule 5.2(j)(5) to provide listing and trading requirements for equity gold shares, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 5.2(j)(5).[41]

Proposed Rule 5.2(j)(6)—Index-Linked Securities Listing Standards

The Exchange is proposing Rule 5.2(j)(6) to provide listing and trading requirements for equity index-linked securities, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive changes between this proposed rule and NYSE Arca Equities Rule 5.2(j)(6): [42]

- To qualify for listing and trading under NYSE Arca Equities Rule 5.2(j)(6), both the issue and issuer of an index-linked security must meet the criteria in NYSE Arca Equities Rule 5.2(j)(1) (Other Securities), with certain specified exceptions. Because the Exchange does not have and is not proposing a rule for

---

[33] NYSE Arca Equities Rules 5.2(a) pertains to applications for admitting securities to list on NYSE Arca and NYSE Arca Equities Rule 5.2(b) pertains to NYSE Arca's unique two-tier listing structure. As these rules pertain to specific listing criteria for NYSE Arca and not trading ETPs pursuant to UTP, the Exchange is not proposing similar rules.

Because NYSE Arca Equities Rules 5.2(c)–(g) relate to listing standards for securities that are not ETPs, the Exchange's listing rules contained in the NYSE Listed Company Manual would apply and it is not proposing rule changes related to such securities.

Finally, NYSE Arca Equities Rule 5.2(h) pertains to Unit Investment Trusts ("UITs"). The Exchange proposes to trade any UITs pursuant to UTP under proposed Rule 5.2(j)(3) (Investment Company Units) or proposed Rule 8.100 (Portfolio Depository Receipts).

[34] NYSE Arca Equities Rule 5.2(j)(1) pertains to "Other Securities" that are not otherwise covered by the requirements contained in the other listing rules of NYSE Arca Equities. As the Exchange is proposing only the rules that are necessary for the Exchange to trade ETPs pursuant to UTP, the Exchange is not proposing a rule comparable to NYSE Arca Equities 5.2(j)(1).

[35] *See,* NYSE Arca Equities Rule 5.2(j)(2). *See, also,* Securities Exchange Act Release No. 50319 (September 7, 2004), 69 FR 55204 (September 13, 2004) (SR–PCX–2004–75); Securities Exchange Act Release No. 56924 (December 7, 2007), 72 FR 70918 (December 13, 2007) (SR–NYSEArca–2007–98); Securities Exchange Act Release No. 58745 (October 7, 2008), 73 FR 60745 (October 14, 2008) (SR–NYSEArca–2008–94).

[36] *See,* NYSE Arca Equities Rule 5.2(j)(3). *See, also,* Securities Exchange Act Release No. 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14); Securities Exchange Act Release No. 40603 (November 3, 1998), 63 FR 59354 (November 3, 1998) (SR–PCX–98–29).

[37] *See* NYSE Arca Equities Rule 5.2(j)(4). *See, also,* Securities Exchange Act Release No. 49532 (April 7, 2004), 69 FR 19593 (April 13, 2004) (SR–PCX–2004–01).

[38] The Exchange will monitor for any changes to the rules of NYSE Arca, and will amend its rules accordingly to conform to the rules of NYSE Arca. The Exchange notes that it is proposing to cross-reference to the rules of an affiliate of the Exchange, which will facilitate monitoring for changes to such rules.

[39] NYSE Arca Options Rule 5.13 sets forth criteria for narrow-based and micro narrow-based indexes on which an options contract may be listed without filing a proposed rule change under Section 19(b) of the Exchange Act.

[40] *See* supra note 38.

[41] *See,* NYSE Arca Equities Rule 5.2(j)(5); *See, also,* Securities Exchange Act Release No. 51245 (February 23, 2005), 70 FR 10731 (March 4, 2005) (SR–PCX–2004–117).

[42] *See,* NYSE Arca Equities Rule 5.2(j)(6); *See, also,* Securities Exchange Act Release No. 54231 (July 27, 2006), 71 FR 44339 (August 4, 2006) (SR–NYSEArca–2006–19); Securities Exchange Act Release No. 59332 (January 30, 2009), 74 FR 6338 (February 6, 2009) (SR–NYSEArca–2008–136); Securities Exchange Act Release No. 52204 (August 3, 2005), 70 FR 46559 (August 10, 2005) (SR–PCX–2005–63).

"Other Securities" comparable to NYSE Arca Rule 5.1(j)(1), the Exchange proposes to reference NYSE Arca Equities Rule 5.1(j)(1) in proposed Rule 5.2(j)(6)(A)(a) establishing the criteria that an issue and issuer must satisfy.[43]

- The listing standards for Equity Index-Linked Securities in NYSE Arca Equities Rule 5.2(j)(6) reference NYSE Arca Options Rule 5.3 [44] in describing the criteria for securities that compose 90% of an index's numerical value and at least 80% of the total number of components. Because the Exchange does not have and is not proposing a rule comparable to NYSE Arca Options Rule 5.3, the Exchange proposes to reference to NYSE Arca Options Rule 5.3 [45] in paragraph (B)(I)(1)(b)(2)(iv) of proposed Rule 5.2(j)(6) establishing the initial listing criteria that an index must meet.[46]

Proposed Rule 5.2(j)(7)—Trust Certificates

The Exchange is proposing Rule 5.2(j)(7) to provide listing and trading requirements for trust certificates, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive change between this proposed rule and NYSE Arca Equities Rule 5.2(j)(7):[47]

- Commentary .08 to NYSE Arca Equities Rule 5.2(j)(7) contains a cross-reference to NYSE Arca Rule 9.2.[48] Because the Exchange does not currently have and is not proposing to add rules that pertain to the opening of accounts that are approved for options trading, the Exchange proposes to require a member organization to ensure that the account of a holder of a Trust Certificate that is exchangeable, at the holder's option, into securities that participate in the return of the applicable underlying asset is approved for options trading in accordance with the rules of a national securities exchange.

Proposed Rule 8P—Trading of Certain Exchange Traded Products

The Exchange proposes to add Rule 8P, which would be substantially identical to Sections 1 and 2 of NYSE Arca Equities Rule 8. These proposed rules would permit the Exchange to trade pursuant to UTP the following: Currency and Index Warrants, Portfolio Depositary Receipts, Trust Issued Receipts, Commodity-Based Trust Shares, Currency Trust Shares, Commodity Index Trust Shares, Commodity Futures Trust Shares, Partnership Units, Paired Trust Shares, Trust Units, Managed Fund Shares, and Managed Trust Securities.[49]

The Exchange proposes to Reserve Rule 8.100(g), to maintain the same rule numbers as the NYSE Arca rules with which it conforms.

The text of Proposed Rule 8P is identical to Sections 1 and 2 of NYSE Arca Equities Rule 8, other than certain non-substantive and technical differences explained below. The Exchange also proposes that all of the General Definitional Term Changes described under proposed Rule 5P above would also apply to proposed Rule 8P.

Proposed Rules 8.1–8.13—Currency and Index Warrants

The Exchange is proposing Rules 8.1–8.13 to provide listing and trading requirements (including sales-practice rules such as those relating to suitability and supervision of accounts) for currency and index warrants, so that they may be traded on the Exchange pursuant to UTP.[50]

In addition to the General Definitional Term Changes described above under proposed Rule 5P, the Exchange is proposing the following non-substantive changes between these proposed rules and NYSE Arca Equities Rules 8.1–8.13 (Currency and Index Warrants):

Proposed Rule 8.1—General

- Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.1.

Proposed Rule 8.2—Definitions

- Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.2.

Proposed Rule 8.3—Listing of Currency and Index Warrants

- NYSE Arca Equities Rule 8.3 references NYSE Arca Equities Rule 5.2(c) to establish the earnings requirements that a warrant issuer is required to substantially exceed. Because the Exchange does not currently have and is not proposing a rule similar to NYSE Arca Equities Rule 5.2(c), the Exchange proposes to include the earnings requirements set forth in Rule 5.2(c) in subparagraph (a) of proposed Rule 8.3.

Proposed Rule 8.4—Account Approval

- The account approval rules of NYSE Arca Equities Rule 8.4 reference NYSE Arca Equities Rule 9.18(b) [51] in describing the criteria that must be met for opening up a customer account for options trading. In proposed Rule 8.4, the Exchange would cross-reference NYSE Arca Equities Rule 9.18(b), which governs doing a public business in options because the Exchange does not trade options and, thus, does not have a comparable rule. As noted earlier, the Exchange will monitor for any changes to this NYSE Arca Equities rule and would update Exchange rules to conform to any changes to NYSE Arca Equities Rules 9.18(b).[52]

Proposed Rule 8.5—Suitability

- The account suitability rules of NYSE Arca Equities Rule 8.5 reference NYSE Arca Equities Rule 9.18(c) [53] in describing rules that apply to recommendations made in stock index, currency index and currency warrants. In proposed Rule 8.5, the Exchange would cross-reference NYSE Arca

---

[43] *See* supra note 38.

[44] NYSE Arca Options Rule 5.3 establishes the criteria for underlying securities of put and call option contracts listed and traded on NYSE Arca.

[45] NYSE Arca Equities Rule 5.2(j)(6)(B)(I)(1)(b)(2)(iv) references "Rule 5.3," but is not clear as to whether the reference is to the rules of NYSE Arca Equities or the rules of NYSE Arca Options. The Exchange proposes to specify in its rule that the reference is to NYSE Arca Options Rule 5.3.

[46] *See* supra note 38.

[47] *See,* NYSE Arca Equities Rule 5.2(j)(7); *See, also,* Securities Exchange Act Release No. 59051 (December 4, 2008), 73 FR 75155 (December 10, 2008) (SR–NYSEArca–2008–123); Securities Exchange Act Release No. 58920 (November 7, 2008), 73 FR 68479 (November 18, 2008) (SR–NYSEArca–2008–123).

[48] Commentary .08 to NYSE Arca Equities Rule 5.2(j)(7) states that Trust Certificates may be exchangeable at the option of the holder into securities that participate in the return of the applicable underlying asset. In the event that the Trust Certificates are exchangeable at the option of the member organization and contains an Index Warrant, then the member organization must ensure that the member organization's account is approved in accordance with Rule 9.2 in order to exercise such rights.

[49] The Exchange is only proposing listing and trading rules necessary to trade ETPs pursuant to UTP. Accordingly, the Exchange is not proposing a rule comparable to NYSE Arca Equities Rule 8.100(g).

[50] NYSE Arca Equities Rules 8.1–8.13 all pertain to the listing and trading requirements (including sales-practice rules such as those relating to suitability and supervision of accounts) for Currency and Index Warrants. *See,* Section 1 of NYSE Arca Equities Rule 8; *See, also,* Securities Exchange Act Release Nos. 44983 (October 25, 2001), 66 FR 55225 (November 1, 2001) (SR–PCX–00–25); 59886 (May 7, 2009), 74 FR 22779 (May 14, 2009) (SR–NYSEArca–2009–39).

[51] NYSE Arca Equities Rule 9.18(b) establishes criteria that must be met to open up a customer account for options trading.

[52] *See* supra note 38.

[53] NYSE Arca Equities Rule 9.18(c) establishes suitability rules that pertain to recommendations in stock index, currency index and currency warrants.

Equities Rule 9.18(c), which governs doing a public business in options because the Exchange does not trade options and, thus, does not have a comparable rule. As noted earlier, the Exchange will monitor for any changes to this NYSE Arca Equities rule and would update Exchange rules to conform to any changes to NYSE Arca Equities Rules 9.18(c).[54]

Proposed Rule 8.6—Discretionary Accounts

- The rules of NYSE Arca Equities Rule 8.6 reference the fact that NYSE Arca Equities Rule 9.6(a)[55] will not apply to customer accounts insofar as they may relate to discretion to trade in stock index, currency index and currency warrants, and that NYSE Arca Equities Rule 9.18(e)[56] will apply to such discretionary accounts instead. The Exchange's discretionary account rule that is equivalent to NYSE Arca Equities Rule 9.6(a) is Rule 408.[57] Accordingly, the Exchange proposes to cross-reference to Rule 408 in proposed Rule 8.6, to establish that the discretionary account rules of Rule 408 would not apply to stock index, currency index and currency warrants.

Proposed Rule 8.7—Supervision of Accounts

- The account supervision rules of NYSE Arca Equities Rule 8.7 reference NYSE Arca Equities Rule 9.18(d)[58] in describing rules that apply to the supervision of customer accounts in which transactions in stock index, currency index or currency warrants are effected. In proposed Rule 8.6, the Exchange would cross-reference NYSE Arca Equities Rule 9.18(d), which governs doing a public business in options because the Exchange does not trade options and, thus, does not have a comparable rule. As noted earlier, the Exchange will monitor for any changes to this NYSE Arca Equities rule and would update Exchange rules to conform to any changes to NYSE Arca Equities Rules 9.18(d).[59]

Proposed Rule 8.8—Customer Complaints

- The customer complaint rules of NYSE Arca Equities Rule 8.8 reference NYSE Arca Equities Rule 9.18(l)[60] in describing rules that apply to customer complaints received regarding stock index, currency index or currency warrants. In proposed Rule 8.8, the Exchange would cross-reference NYSE Arca Equities Rule 9.18(l), which governs doing a public business in options because the Exchange does not trade options and, thus, does not have a comparable rule. As noted earlier, the Exchange will monitor for any changes to this NYSE Arca Equities rule and would update Exchange rules to conform to any changes to NYSE Arca Equities Rules 9.18(l).[61]

Proposed Rule 8.9—Prior Approval of Certain Communications to Customers

- The rules pertaining to communications to customers regarding stock index, currency index and currency warrants described in NYSE Arca Equities Rule 8.9 reference NYSE Arca Equities Rule 9.28.[62] In proposed Rule 8.8, the Exchange would cross-reference NYSE Arca Equities Rule 9.28, which governs advertisements, market letters and sales literature relating to options because the Exchange does not trade options and, thus, does not have a comparable rule. As noted earlier, the Exchange will monitor for any changes to this NYSE Arca Equities rule and would update Exchange rules to conform to any changes to NYSE Arca Equities Rules 9.28.[63]

Proposed Rule 8.10—Position Limits

- Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.10.

Proposed Rule 8.11—Exercise Limits

- Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.11.

Proposed Rule 8.12—Trading Halts or Suspensions

- Other than with respect to the General Definitional Term Changes described above, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.12.

Proposed Rule 8.13—Reporting of Warrant Positions

- The Exchange proposes to correct a typographical error in NYSE Arca Equities Rule 8.13. Proposed Rule 8.13 would read "whenever a report shall be required to be filed with respect to an account pursuant to this Rule, the member organization filing the report shall file with the Exchange such additional periodic reports with respect to such account as the Exchange may from time to time prescribe," rather than "whenever a report shall be required to be filed with respect to an account pursuant to this Rule, the member organization filing the same file with the Exchange such additional periodic reports with respect to such account as the Exchange may from time to time prescribe," as in current NYSE Arca Equities Rule 8.13.

Proposed Rule 8.100—Portfolio Depositary Receipts

The Exchange is proposing Rule 8.100 to provide listing and trading requirements for portfolio depositary receipts, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.100.[64]

Proposed Rule 8.200—Trust Issued Receipts

The Exchange is proposing Rule 8.200 to provide listing and trading requirements for trust issued receipts, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.200.[65]

---

[54] *See* supra note 38.

[55] NYSE Arca Equities Rule 9.6(a) establishes rules pertaining to discretion as to customer accounts for equity trading.

[56] NYSE Arca Equities Rule 9.18(e) establishes rules pertaining to discretion as to customer accounts for options trading.

[57] *See* Rule 408 pertaining to the rules of the Exchange with regard to discretionary power in customer accounts.

[58] NYSE Arca Equities Rule 9.18(d) establishes account supervision rules that apply to the supervision of customer accounts in which transactions in stock index, currency index and currency warrants are effected.

[59] *See* supra note 38.

[60] NYSE Arca Equities Rule 9.18(l) establishes rules that apply to customer complaints received regarding stock index, currency index or currency warrants.

[61] *See* supra note 38.

[62] NYSE Arca Equities Rule 9.28 establishes rules regarding advertisements, sales literature and educational material issued to any customer or member of the public pertaining to stock index, currency index or currency warrants.

[63] *See* supra note 38.

[64] *See,* NYSE Arca Equities Rule 8.100; *See, also,* Securities Exchange Act Release No. 39461 (December 17, 1997), 62 FR 67674 (December 29, 1997) (SR–PCX–97–35); Securities Exchange Act Release No. 39188 (October 2, 1997), 62 FR 53373 (October 14, 1997) (SR–PCX–97–35); Securities Exchange Act Release No. 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14).

[65] *See,* NYSE Arca Equities Rule 8.200; *See, also,* Securities Exchange Act Release No. 58162 (July 15, 2008), 73 FR 42391 (July 21, 2008) (SR–NYSEArca–2008–73); Securities Exchange Act Release No.

Proposed Rule 8.201—Commodity-Based Trust Shares

The Exchange is proposing Rule 8.201 to provide listing and trading requirements for commodity-based trust shares, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.201.[66]

Proposed Rule 8.202—Currency Trust Shares

The Exchange is proposing Rule 8.202 to provide listing and trading requirements for currency trust shares, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.202.[67]

Proposed Rule 8.203—Commodity Index Trust Shares

The Exchange is proposing Rule 8.203 to provide listing and trading requirements for commodity index trust shares, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive change between this proposed rule and NYSE Arca Equities Rule 8.203:[68]

- Correction of a typographical error in NYSE Arca Equities Rule 8.203(d), so that proposed Rule 8.203(d) reads "one or more" in the first sentence, rather than "one more more," as is currently drafted in NYSE Arca Equities Rule 8.203(d).

Proposed Rule 8.204—Commodity Futures Trust Shares

The Exchange is proposing Rule 8.204 to provide listing and trading requirements for commodity futures trust shares, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.204.[69]

Proposed Rule 8.300—Partnership Units

The Exchange is proposing Rule 8.300 to provide listing and trading requirements for partnership units, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.300.[70]

Proposed Rule 8.400—Paired Trust Shares

The Exchange is proposing Rule 8.400 to provide listing and trading requirements for paired trust shares, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive change between this proposed rule and NYSE Arca Equities Rule 8.400:[71]

- To be consistent with the Exchange's definitions proposed in Rule 5.1(b), the Exchange proposes to substitute the terms "security" and "equity securities" (as such terms are defined in proposed Rule 5.1(b)[72]) in subparagraph (a) of proposed Rule 8.400[73] instead of the terms "security," "securities" and "derivative products" (as used in the rules of NYSE Arca Equities) to refer to the definition of Paired Trust Shares. The Exchange proposes this change because it believes it is more accurate to refer to paired trust shares as securities and equity securities.
- Correction of a typographical error in NYSE Arca Equities Rule 8.400(a), so that proposed Rule 8.400(a) reads "as such terms are used in Rule 5.1(b)" in the last sentence, rather than "as such terms are used in the Rule 5.1(b)" as is currently drafted in NYSE Arca Equities Rule 8.400(a).

Proposed Rule 8.500—Trust Units

The Exchange is proposing Rule 8.500 to provide listing and trading requirements for trust units, so that they may be traded on the Exchange pursuant to UTP.

In addition to the General Definitional Term Changes described above, the Exchange is proposing the following non-substantive change between this proposed rule and NYSE Arca Equities Rule 8.500:[74]

- To be consistent with the Exchange's definitions proposed in Rule 5.1(b), the Exchange proposes to substitute the terms "security" and "equity securities" (as such terms are defined in proposed Rule 5.1(b)[75]) in subparagraph (a) of proposed Rule 8.500[76] instead of the terms "security," "securities" and "derivative products" (as used in the rules of NYSE Arca Equities) to refer to the definition of Trust Units. The Exchange proposes this change because it believes it is more accurate to refer to trust units as securities and equity securities.

Proposed Rule 8.600—Managed Fund Shares

The Exchange is proposing Rule 8.600 to provide listing and trading requirements for managed fund shares,

---

44182 (April 16, 2001), 66 FR 21798 (April 16, 2001) (SR–PCX–2001–01).

[66] *See,* NYSE Arca Equities Rule 8.201; *See, also,* Securities Exchange Act Release No. 51067 (January 21, 2005), 70 FR 3952 (January 27, 2005) (SR–PCX–2004–132).

[67] *See,* NYSE Arca Equities Rule 8.202; *See, also,* Securities Exchange Act Release No. 60065 (June 8, 2009), 74 FR 28310 (June 15, 2009) (SR–NYSEArca–2009–47); Securities Exchange Act Release No. 53253 (February 8, 2006), 71 FR 8029 (February 15, 2006) (SR–PCX–2005–123).

[68] *See,* NYSE Arca Equities Rule 8.203; *See, also,* Securities Exchange Act Release No. 54025 (June 21, 2006), 71 FR 36856 (June 28, 2006) (SR–NYSEArca–2006–12).

[69] *See,* NYSE Arca Equities Rule 8.204; *See, also,* Securities Exchange Act Release No. 57838 (May 20, 2008), 73 FR 30649 (May 28, 2008) (SR–NYSEArca–2008–09); Securities Exchange Act Release No. 57636 (April 8, 2008), 73 FR 20344 (April 15, 2008) (SR–NYSEArca–2008–09).

[70] *See,* NYSE Arca Equities Rule 8.300; *See, also,* Securities Exchange Act Release No. 53875 (May 25, 2006), 71 FR 32164 (January 2, 2006) (SR–NYSEArca–2006–11).

[71] *See,* NYSE Arca Equities Rule 8.400; *See, also,* Securities Exchange Act Release No. 55033 (December 29, 2006), 72 FR 1253 (January 10, 2007) (SR–NYSEArca–2006–75); Securities Exchange Act Release No. 58312 (August 5, 2008), 73 FR 46689 (August 11, 2008) (SR–NYSEArca–2008–63).

[72] Proposed Rule 5.1(b) defines the term "security" to mean any security as defined in Rule 3(a)(10) under the Act and the term "equity security" to include any equity security defined as such pursuant to Rule 3a11–1 under the Act.

[73] NYSE Arca Equities Rule 8.400(a) reads as follows:

"(a) Applicability. The provisions in this Rule are applicable only to Paired Trust Shares. In addition, except to the extent inconsistent with this Rule, or unless the context otherwise requires, the rules and procedures of the Board of Directors shall be applicable to the trading on the Corporation of such securities. Paired Trust Shares are included within the definition of "security," "securities" and "derivative products" as such terms are used in the Rules of the Corporation."

[74] *See,* NYSE Arca Equities Rule 8.500; *See, also,* Securities Exchange Act Release No. 57059 (December 28, 2007), 73 FR 909 (January 4, 2008) (SR–NYSEArca–2006–76); Securities Exchange Act Release No. 63129 (October 19, 2010), 75 FR 65539 (October 25, 2010) (SR–NYSEArca–2010–91).

[75] *See* supra note 72.

[76] NYSE Arca Equities Rule 8.500(a) reads as follows:

"(a) Applicability. The provisions in this Rule are applicable only to Trust Units. In addition, except to the extent inconsistent with this Rule, or unless the context otherwise requires, the rules and procedures of the Board of Directors shall be applicable to the trading on the Corporation of such securities. Trust Units are included within the definition of "security," "securities" and "derivative products" as such terms are used in the Rules of the Corporation."

so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.600.[77]

Proposed Rule 8.700—Managed Trust Shares

The Exchange is proposing Rule 8.700 to provide listing and trading requirements for managed fund shares, so that they may be traded on the Exchange pursuant to UTP.

Other than with respect to the General Definitional Term Changes described above under proposed Rule 5P, there are no differences between this proposed rule and NYSE Arca Equities Rule 8.700.[78]

Proposed Rule 7.18—Requirements for Halts on Pillar Platform

In conjunction with the implementation of the Pillar trading platform for trading of securities pursuant to UTP, the Exchange proposes new Rule 7.18, under Rule 7P, which would govern trading halts in symbols trading on the Pillar platform.

Since the Exchange is only proposing rules in this filing pertaining to trading pursuant to UTP on the Pillar platform, the Exchange is only proposing Rules 7.18(a) and (d)(1)(B), which pertain to trading halts of securities traded pursuant to UTP and UTP Exchange Traded Products. The Exchange proposes to Reserve Rules 7.18(b)–(c)[79] and Rules 7.18(d)(1)(A) and (C),[80] to maintain the same rule numbers as the NYSE Arca rules with which it conforms.

Other than with respect to the proposed General Definitional Term Changes described above, there are no differences between proposed Rules 7.18(a) and (d)(1)(B) and NYSE Arca Equities Rules 7.18P(a) and (d)(1)(B).

Finally, proposed Rules 7.18(a) and (d)(1)(B) would use the terms and definitions that were added in the Pillar Framework Filing and proposed as new Rules 1.1(aaa) and (bbb), described above. The Exchange also proposes to define the term "UTP regulatory halt" in Rule 1.1(kk).[81] Proposed Rule 1.1(kk) would define the term "UTP Regulatory Halt" to mean a trade suspension, halt, or pause called by the UTP Listing Market[82] in a UTP Security[83] that requires all market centers to halt trading in that security.[84]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[85] in general, and furthers the objectives of Section 6(b)(5) of the Act,[86] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest by providing for the trading of securities, including UTP Exchange Traded Products, on the Exchange pursuant to UTP, subject to consistent and reasonable standards. Accordingly, the proposed rule change would contribute to the protection of investors and the public interest because it may provide a better trading environment for investors and, generally, encourage greater competition between markets.

The Exchange believes the proposed rule change also supports the principals of Section 11A(a)(1)[87] of the Act in that it seeks to ensure the economically efficient execution of securities transactions and fair competition among brokers and dealers and among exchange markets. The proposed rule change also supports the principles of Section 12(f) of the Act, which govern the trading of securities pursuant to a grant of unlisted trading privileges consistent with the maintenance of fair and orderly markets, the protection of investors and the public interest, and the impact of extending the existing markets for such securities.

The Exchange believes that the proposed rule change is consistent with these principles. By providing for the trading of securities on the Exchange on a UTP basis, the Exchange believes its proposal will lead to the addition of liquidity to the broader market for these securities and to increased competition among the existing group of liquidity providers. The Exchange also believes that, by so doing, the proposed rule change would encourage the additional utilization of, and interaction with, the exchange market, and provide market participants with improved price discovery, increased liquidity, more competitive quotes and greater price improvement for securities traded pursuant to UTP.

The Exchange further believes that enhancing liquidity by trading securities on a UTP basis would help raise investors' confidence in the fairness of the market, generally, and their transactions in particular. As such, the general UTP trading rule would foster cooperation and coordination with persons engaged in facilitating securities transactions, enhance the mechanism of a free and open market, and promote fair and orderly markets in securities on the Exchange.

In addition, the trading criteria set forth in proposed Rule 5.1(a) is intended to protect investors and the public interest. The requirements for trading securities pursuant to UTP, as proposed herein in a single, consolidated Rule 5.1(a), are at least as stringent as those of any other national securities exchange and, specifically, are based on the consolidated rules for trading UTP securities established by other national securities exchanges.[88] Consequently, the proposed rule change is consistent with the protection of investors and the public interest. Additionally, the proposal is designed to prevent fraudulent and manipulative acts and practices, as trading pursuant to UTP is subject to existing Exchange trading rules, together with specific requirements for registered market makers, books and record production, surveillance procedures, suitability and prospectus requirements, and requisite the Exchange approvals, all set forth above.

---

[77] *See,* NYSE Arca Equities Rule 8.600; *See also,* Securities Exchange Act Release No. 57395 (February 28, 2008), 73 FR 11974 (March 5, 2008) (SR–NYSEArca–2008–25); Securities Exchange Act Release No. 57619 (April 4, 2008), 73 FR 19544 (April 10, 2008) (SR–NYSEArca–2008–25).

[78] *See,* NYSE Arca Equities Rule 8.700; *See, also,* Securities Exchange Act Release No. 60064 (June 8, 2009), 74 FR 28315 (June 15, 2009) (SR–NYSEArca–2009–30); Securities Exchange Act Release No. 59835 (April 28, 2009), 74 FR 21041 (May 6, 2009) (SR–NYSEArca–2009–30).

[79] Because NYSE Arca Equities Rules 7.18P(b)–(c) pertain specifically to specific NYSE Arca order types that the Exchange has not yet proposed, the Exchange proposes such sub-sections of proposed Rule 7.18 on a "reserved" basis, until such later time when the Exchange proposes rules regarding order types to be operative on the Pillar platform.

[80] Since NYSE Arca Equities Rules 7.18(d)(1)(A) and (C) pertain to trading outside of normal business hours, the Exchange proposes such sub-sections of proposed Rule 7.18 on a "reserved" basis. If the Exchange determines to expand its trading hours outside of normal business hours it would propose amendments to Rule 7.18.

[81] The Pillar Framework Filing added Rule 1.1(kk) on a "reserved" basis.

[82] *See,* proposed Rule 1.1(jj).

[83] *See,* proposed Rule 1.1(ii).

[84] This proposed definition is identical to the definition of "UTP Regulatory Halt" in NYSE Arca Equities Rule 1.1(kk).

[85] 15 U.S.C. 78f(b).

[86] 15 U.S.C. 78f(b)(5).

[87] 15 U.S.C. 78k–1(a)(1).

[88] *See* NSX Rule 15.9 and Securities Exchange Act Release No. 57448 (March 6, 2008), 73 FR 13597 (March 13, 2008) (SR–NSX–2008–05); Phlx Rule 803(o) and Securities Exchange Act Release No. 57806 (May 9, 2008), 73 FR 28541 (May 16, 2008) (SR–Phlx–2008–34); ISE Rule 2101 and Securities Exchange Act Release No. 57387 (February 27, 2008), 73 FR 11965 (March 5, 2008) (SR–ISE–2007–99).

The proposal is also designed to promote just and equitable principles of trade by way of initial and continued listing standards which, if not maintained, will result in the discontinuation of trading in the affected products. These requirements, together with the applicable Exchange trading rules (which apply to the proposed products), ensure that no investor would have an unfair advantage over another respecting the trading of the subject products. On the contrary, all investors will have the same access to, and use of, information concerning the specific products and trading in the specific products, all to the benefit of public customers and the marketplace as a whole.

The proposal is intended to ensure that investors receive up-to-date information on the value of certain underlying securities and indices in the products in which they invest, and protect investors and the public interest, enabling investors to: (i) Respond quickly to market changes through intraday trading opportunities; (ii) engage in hedging strategies; and (iii) reduce transaction costs for trading a group or index of securities.

Furthermore, the proposal is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system by adopting listing standards that will lead ultimately to the trading, whether by listing or pursuant to UTP, of the proposed new products on the Exchange, just as they are currently traded on other exchanges. The proposed changes do nothing more than match Exchange rules with what is currently available on other exchanges. The Exchange believes that by conforming its rules and allowing listing opportunities on the Exchange that are already allowed by rule on another market, the proposal would offer another venue for listing and trading Exchange Traded Products and thereby promote broader competition among exchanges. The Exchange believes that individuals and entities permitted to make markets on the Exchange in the proposed new products should enhance competition within the mechanism of a free and open market and a national market system, and customers and other investors in the national market system should benefit from more depth and liquidity in the market for the proposed new products.

The proposed change is not designed to address any competitive issue, but rather to adopt new rules that are word-for-word identical to the rules of NYSE Arca (other than with respects[sic] to certain non-substantive and technical amendments described above), to support the Exchange's new Pillar trading platform. As discussed in detail above, with this rule filing, the Exchange is not proposing to change its core functionality, but rather to adopt a rule numbering framework and rules based on the rules of NYSE Arca. The Exchange believes that the proposed rule change would promote consistent use of terminology to support the Pillar trading platform on both the Exchange and its affiliate, NYSE Arca, thus making the Exchange's rules easier to navigate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the current variances between the Exchange's listing rules and the listing rules of other exchanges limit competition in that there are certain products that the Exchange cannot trade, whether by listing or pursuant to UTP, while other exchanges can list and trade such products. Thus, approval of the proposed rule change will promote competition because it will allow the Exchange to compete with other national securities exchanges for the trading of securities pursuant to UTP.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2016–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–44 and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[89]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16605 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

---

[89] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78260; File No. SR–NYSEArca–2016–95]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fee Schedule

July 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 1, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule ("Fee Schedule"). The Exchange proposes to implement the fee change effective July 1, 2016. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify certain fees charged for Options Trading Permits (each an "OTP") and to decrease the fee charged to registered floor personnel who are not subject to an OTP Fee. The Exchange proposes to implement the changes effective July 1, 2016.

Currently, the Exchange charges Floor Brokers, Office, and Clearing participants a monthly fee of $1,000 for the first OTP and $250 per month for each additional OTP.[3] The Exchange proposes to reduce the monthly OTP fee charged to Floor Brokers to $500, which is consistent with trading permit fees charged to similarly situated market participants on other options markets.[4] The Exchange would continue to charge Office and Clearing participants a monthly OTP Fee of $1,000.

In addition, the Exchange proposes to eliminate the reduced ($250) monthly for any of these participants and to delete the language stating that additional OTPs utilized by a Floor Broker would not enable a second Floor Broker to operate on the Floor. As an initial matter, Office and Clearing participants would rarely, if ever, require a second OTP, so eliminated the reduced $250 would have little to no practical impact on these participants. Regarding Floor Brokers, historically each Floor Broker could only log in to a single Floor Broker Order Capture Device ("FBOCD"), which provided access to the Exchange-sponsored Floor Broker Order Capture System.[5] This limitation was required because the Floor Broker's log-in was used to populate "Executing Broker" fields within the FBOCD system. Thus, in order to conduct business at various locations on the Floor, Floor Brokers needed to be able to log in to multiple FBOCD and therefore would request additional OTPs. However, these additional OTPs were assigned to the same individual Floor Broker and were not used to provide for a second Floor Broker to operate on the Floor. In recent years, however, the Exchange has upgraded and modified its System such that each log-in permits Floor Brokers access to the System from any FBOCD, whether located in a Floor Broker's booth or a general access device located on the Trading Floor. As a result of this improved remote access, Floor Brokers no longer require additional OTPs to conduct business on the Floor. Therefore, the Exchange proposes to eliminate the provision and the associated reduced Fee.

The Exchange also proposes to reduce the Options Floor Access Fee ("Access Fee") that is currently charged to registered personnel who work on the Floor, but do not require an OTP as they do not execute trades. The Exchange proposes to reduce the monthly Access Fee from $130 to $125, which is consistent with fees charged by other options exchanges for similarly situated floor personnel.[6]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that modifying the OTP Fee for Floor Brokers is reasonable, equitable, and not unfairly discriminatory because the reduced fee would apply to all Floor Brokers who, unlike other market participants (*i.e.,* Office and Clearing Participants), are restricted to conduct business only on a manual basis on the Trading Floor. The Exchange believes that the proposed changes would encourage competition, including by reducing the overhead costs for Floor Brokers so that they may conduct a more competitive business attracting manual orders to the Exchange, which additional volume and liquidity would benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. Further, because Office and Clearing Participants rarely if ever require a second OTP, the proposed removal of the reduced ($250) fee would have little to no impact on them. Additionally, the proposed fee changes is [sic] reasonable because it is similar to trading permit fees charged by another options exchange to similarly situated market participants.[9]

The Exchange also believes that the proposed modification in the Access

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Fee Schedule, *available here, https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf.*

[4] *See* NYSE Amex Options Fee Schedule, Section III.A. (Monthly ATP Fees), available here, *https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf (charging Floor Brokers monthly fee of $500 per ATP).*

[5] The FBOCD is used by Floor Brokerage operations to comply with the requirements of Rule 6.67, Order Format and System Entry Requirements, namely, the systemization of order details and electronic tracking of all events in the life of an order, up to and including cancellation or execution.

[6] *See supra* n. 5 [sic], NYSE Amex Options Fee Schedule, Section III.A. (Floor Access Fee) (charging $125 per month for all registered Floor personnel that do not pay Monthly ATP Fees).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] *See supra* n. 5 [sic].

Fees is reasonable, equitable, and not unfairly discriminatory as the Access Fee is charged to all registered personnel that operate on the Floor but do not execute transactions. The proposed fee is equitable and not discriminatory as it applies equally to all similarly situated individuals. Additionally, the proposed fee is reasonable because it is similar to fees charged by another options exchange to similarly situated floor personnel.[10]

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[11] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed changes would encourage competition, including by reducing the overhead costs for Floor Brokers so that they may conduct a more competitive business attracting manual orders to the Exchange, which would make the Exchange a more competitive venue for, among other things, order execution and price discovery.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[12] of the Act and subparagraph (f)(2) of Rule 19b–4[13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–NYSEArca–2016–95 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSEArca–2016–95. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2016–95, and should be submitted on or before August 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–16602 Filed 7–13–16; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Boathouse Capital II, LP, License No. 03/03–0264; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Boathouse Capital II, L.P., 353 West Lancaster Avenue, Suite 200, Wayne, PA 19087, a Federal Licensee under the Small Business Investment Act of 1958, as amended ("the Act"), in connection with the financing of CalNet Technology Group, Inc., 420 3rd Ave NW., Hickory, NC 28601, has sought an exemption under Section 312 of the Act and 13 CFR 107.730 financings which constitute conflicts of interest of the Small Business Administration ("SBA") Rules and Regulations. Boathouse Capital II, LP proposes to provide debt financing to CalNet Technology Group, Inc., owned by Boathouse Capital, LP, an associate as defined in Sec. 105.50 of the regulations. Therefore this transaction is considered a conflict of interest requiring SBA's prior written exemption.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Mark Walsh,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2016–16701 Filed 7–13–16; 8:45 am]

BILLING CODE 8025–01–P

---

[10] *See supra* n. 7 [sic].

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9637]

Notice of 30-Day Public Comment Period Regarding the National Interest Determination for NuStar Logistics, L.P.'s Presidential Permit Application

AGENCY: Department of State.

ACTION: Notice of solicitation of comments.

SUMMARY: NuStar Logistics, L.P. ("NuStar") applied for an amended Presidential Permit to authorize the operation and maintenance of existing pipeline facilities at the United States-Mexico border originally authorized under a 2003 Presidential Permit (the "Dos Loredos Pipeline"). Specifically, NuStar requested that the U.S. Department of State ("State Department") amend the 2003 Presidential Permit to: Reflect NuStar's name change from Valero Logistics Operations, L.P. to NuStar Logistics, L.P. as owner and operator of the Dos Loredos Pipeline; and allow the import and export of a wider range of refined petroleum products across the international border, including regular and premium gasoline, kerosene, and diesel. The 2003 Presidential Permit only allows the shipment of liquefied petroleum gas (LPG) through the existing 8⅝-inch diameter pipeline for approximately 10.6 miles from the NuStar terminal in Laredo, Texas to a location on the Rio Grande known as "La Bota."

After consulting with the public and interested agencies, on May 11, 2016, the State Department approved a Final Supplemental Environmental Assessment ("SEA") for the Dos Laredos Pipeline and Finding of No Significant Impact ("FONSI"). Background information related to the application, including the SEA and FONSI may be found at: *http://www.state.gov/e/enr/applicant/applicants/index.htm.*

Executive Order 13337 (69 FR 25299) calls on the Secretary of State, or his designee, to determine if issuance of a Presidential Permit would serve the national interest. This decision will take into account a wide range of factors, including energy security; environmental, cultural, and economic impacts; foreign policy; and compliance with relevant federal regulations and issues.

The State Department invites members of the public to comment on any factor they deem relevant to the national interest determination that will be made for this permit application. Along with other factors such as those listed above, these comments will be considered in the final national interest determination. The public comment period will end 30 days from the publication of this notice.

Comments are not private. They will be posted on the site *http://www.regulations.gov.* The comments will not be edited to remove identifying or contact information, and the State Department cautions against including any information that one does not want publicly disclosed. The State Department requests that any part soliciting or aggregating comments received from other persons for submission to the State Department inform those persons that the State Department will not edit their comments to remove identifying or contact information, and that they should not include any information in their comments that they do not want publicly disclosed.

DATES: Comments must be submitted no later than August 15, 2016 at [TIME].

ADDRESSES: For reasons of efficiency, the State Department encourages the electronic submission of comments through the federal government's eRulemaking Portal (*http://www.regulations.gov*), enter the Docket No. DOS–2016–0051 and follow the prompts to submit a comment.

The State Department also will accept comments submitted in hard copy by mail and postmarked no later than August 15, 2016. Please note that standard mail delivery to the State Department can be delayed due to security screening. To submit comments by mail, use the following address: Office of Energy Diplomacy, Energy Resources Bureau (ENR/EDP/EWA) Department of State 2201 C St. NW., Ste 4428, Attn: Sydney Kaufman, Washington, DC 20520.

Dated: July 7, 2016.

R. Chris Davy,

Deputy Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resource, Department of State.

[FR Doc. 2016–16678 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 9635]

Notice of 30-Day Public Comment Period Regarding the National Interest Determination for NuStar Logistics, LP Presidential Permit Application

AGENCY: Department of State.

ACTION: Notice of solicitation of comments.

SUMMARY: NuStar Logistics, LP ("NuStar") applied for a Presidential Permit to authorize the construction, connection, operation, and maintenance of pipeline facilities for the export and import of petroleum products, including diesel, gasoline, jet fuel, liquefied petroleum gas ("LPG") and natural gas liquids ("NGLs"). The application requests authorization from the Department of State ("State Department") for a new 10-inch outer diameter pipeline and associated facilities ("New Burgos Pipeline") in the same right of way as an existing 8-inch pipeline for which a Presidential Permit was issued on February 17, 2006 ("Existing Burgos Pipeline").[1] Both pipelines would connect the Petroleos Mexicanos Burgos Gas Plant near Reynosa, Tamaulipas, Mexico and the NuStar terminal near Edinburg, Texas in Hidalgo County, Texas at the United States-Mexico border.

After consulting with the public and interested agencies, on June 16, 2016, the State Department approved a Final Environmental Assessment ("EA") for the Existing Burgos Pipeline and New Burgos Pipeline and a Finding of No Significant Impact ("FONSI"). Background information related to the application, including the EA and FONSI may be found at: *http://www.state.gov/e/enr/applicant/applicants/index.htm.*

Executive Order 13337 (69 FR 25299) calls on the Secretary of State, or his designee, to determine if issuance of a Presidential Permit would serve the national interest. This decision will take into account a wide range of factors, including energy security; environmental, cultural, and economic impacts; foreign policy; and compliance with relevant federal regulations and issues.

The State Department invites members of the public to comment on any factor they deem relevant to the national interest determination that will be made for this permit application. Along with other factors such as those listed above, these comments will be considered in the final national interest determination. The public comment period will end 30 days from the publication of this notice.

---

[1] Per another **Federal Register** Notice published today, the Department has separately requested the public's views with regard to NuStar's application for an amended Presidential Permit for the Existing Burgos Pipeline that would: (1) Reflect NuStar's name change from Valero Logistics Operations, LP to NuStar Logistics, LP as the owner and operator of the Existing Burgos Pipeline and (2) authorize the Existing Burgos Pipeline border facilities to transport a broader range of petroleum products than allowed by the 2006 Presidential Permit, including LPG and NGLs.

Comments are not private. They will be posted on the site *http://www.regulations.gov*. The comments will not be edited to remove identifying or contact information, and the State Department cautions against including any information that one does not want publicly disclosed. The State Department requests that any part soliciting or aggregating comments received from other persons for submission to the State Department inform those persons that the State Department will not edit their comments to remove identifying or contact information, and that they should not include any information in their comments that they do not want publicly disclosed.

DATES: Comments must be submitted no later than August 15, 2016 at 11:59 p.m.

ADDRESSES: For reasons of efficiency, the State Department encourages the electronic submission of comments through the federal government's eRulemaking Portal (*http://www.regulations.gov*), enter the Docket No. DOS–2016–0049, and follow the prompts to submit a comment.

The State Department also will accept comments submitted in hard copy by mail and postmarked no later than August 15, 2016. Please note that standard mail delivery to the State Department can be delayed due to security screening. To submit comments by mail, use the following address: Office of Energy Diplomacy, Energy Resources Bureau (ENR/EDP/EWA) Department of State, 2201 C St. NW., Ste. 4428, Attn: Sydney Kaufman, Washington, DC 20520.

Dated: July 7, 2016.

R. Chris Davy,

Deputy Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resource, Department of State.

[FR Doc. 2016–16676 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 9632]

Executive Order 13224 Designation of Aslan Avgazarovich, aka Aslan Byutukayev, aka Aslan Byutukaev, aka Emir Khamzat, aka Amir Khamzat, aka Khamzat Chechensky, aka Hamzat as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Aslan Avgazarovich Byutukaev, also known as Aslan Byutukayev, also known as Aslan Byutukaev, also known as Emir Khamzat, also known as Amir Khamzat, also known as Khamzat Chechensky, also known as Hamzat committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: May 16, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–16572 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9634]

Certification Pursuant to Section 7045(a)(3)(B) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (DIV. K, Pub. L. 114–113)

By virtue of the authority vested in me as the Deputy Secretary of State by Department of State Delegation of Authority 245–1, and pursuant to section 7045(a)(3)(B) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2016 (Div. K, Pub. L. 114–113), I hereby certify the central government of Guatemala is taking effective steps to:

- Establish an autonomous, publicly accountable entity to provide oversight of the Plan of the Alliance for Prosperity in the Northern Triangle of Central America (Plan);
- combat corruption, including investigating and prosecuting government officials credibly alleged to be corrupt;
- implement reforms, policies, and programs to improve transparency and strengthen public institutions, including increasing the capacity and independence of the judiciary and the Office of the Attorney General;
- establish and implement a policy that local communities, civil society organizations (including indigenous and other marginalized groups), and local governments are consulted in the design, and participate in the implementation and evaluation of, activities of the Plan that affect such communities, organizations, and governments;
- counter the activities of criminal gangs, drug traffickers, and organized crime;
- investigate and prosecute in the civilian justice system members of military and police forces who are credibly alleged to have violated human rights, and ensure that the military and police are cooperating in such cases;
- cooperate with commissions against impunity, as appropriate, and with regional human rights entities;
- support programs to reduce poverty, create jobs, and promote equitable economic growth in areas contributing to large numbers of migrants;
- establish and implement a plan to create a professional, accountable civilian police force and curtail the role of the military in internal policing;
- protect the right of political opposition parties, journalists, trade unionists, human rights defenders, and other civil society activists to operate without interference;
- increase government revenues, including by implementing tax reforms and strengthening customs agencies; and
- resolve commercial disputes, including the confiscation of real property, between U.S. entities and such government.

This certification shall be published in the **Federal Register** and, along with the accompanying Memorandum of Justification, shall be reported to Congress.

Dated: June 28, 2016.

Antony J. Blinken,

Deputy Secretary of State.

[FR Doc. 2016–16679 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–29–P

DEPARTMENT OF STATE

[Public Notice: 9636]

Notice of 30 Day Public Comment Period Regarding the National Interest Determination for NuStar Logistics, LP Presidential Permit Application

AGENCY: Department of State.

ACTION: Notice of solicitation of comments.

SUMMARY: NuStar Logistics, LP ("NuStar") applied for an amended Presidential Permit from the Department of State ("State Department") to authorize the operation and maintenance of existing pipeline facilities (the "Existing Burgos Pipeline") at the United States-Mexico border. Specifically, NuStar requested that the Department amend the 2006 Presidential Permit to: (1) Reflect NuStar's name change from Valero Logistics Operations, LP to NuStar Logistics, LP as the owner and operator of the Existing Burgos Pipeline and (2) authorize the Existing Burgos Pipeline border facilities to transport a broader range of petroleum products than allowed by the 2006 Presidential Permit, including diesel, gasoline, jet fuel, liquefied petroleum gas, and natural gas liquids. The 2006 Presidential Permit only allows transportation of light naphtha.

After consulting with the public and interested agencies, on June 10, 2016, the State Department approved a Final Environmental Assessment ("EA") for the Existing Burgos Pipeline and New Burgos Pipeline and a Finding of No Significant Impact ("FONSI"). Background information related to the application, including the EA and FONSI may be found at: *http://www.state.gov/e/enr/applicant/applicants/index.htm.*

Executive Order 13337 (69 FR 25299) calls on the Secretary of State, or his designee, to determine if issuance of a Presidential Permit would serve the national interest. This decision will take into account a wide range of factors, including energy security; environmental, cultural, and economic impacts; foreign policy; and compliance with relevant federal regulations and issues.

The State Department invites members of the public to comment on any factor they deem relevant to the national interest determination that will be made for this permit application. Along with other factors such as those listed above, these comments will be considered in the final national interest determination. The public comment period will end 30 days from the publication of this notice.

Comments are not private. They will be posted on the site *http://www.regulations.gov.* The comments will not be edited to remove identifying or contact information, and the State Department cautions against including any information that one does not want publicly disclosed. The State Department requests that any part soliciting or aggregating comments received from other persons for submission to the State Department inform those persons that the State Department will not edit their comments to remove identifying or contact information, and that they should not include any information in their comments that they do not want publicly disclosed.

DATES: Comments must be submitted no later than August 15, 2016 at 11:59 p.m.

ADDRESSES: For reasons of efficiency, the State Department encourages the electronic submission of comments through the federal government's eRulemaking Portal (*http://www.regulations.gov*), enter the Docket No. DOS–2016–0050 and follow the prompts to submit a comment.

The State Department also will accept comments submitted in hard copy by mail and postmarked no later than August 15, 2016. Please note that standard mail delivery to the State Department can be delayed due to security screening. To submit comments by mail, use the following address: Office of Energy Diplomacy, Energy Resources Bureau (ENR/EDP/EWA) Department of State 2201 C St. NW., Ste. 4428, Attn: Sydney Kaufman, Washington, DC 20520.

Dated: July 7, 2016.

R. Chris Davy,

Deputy Director, Office of Europe, Western Hemisphere and Africa, Bureau of Energy Resource, Department of State.

[FR Doc. 2016–16677 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 9633]

Executive Order 13224 Designation of Ayrat Nasimovich Vakhitov, aka Aiat Nasimovich Vahitov, aka Airat Vakhitov, aka Aryat Vakhitov, aka Airat Wakhitov, aka Taub Ayrat Vakhitov, aka Salman Bulgarsky, aka Salman Bulgarskiy, as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Ayrat Nasimovich Vakhitov, also known as Aiat Nasimovich Vahitov, also known as Airat Vakhitov, also known as Aryat Vakhitov, also known as Airat Wakhitov, also known as Taub Ayrat Vakhitov, also known as Salman Bulgarsky, also known as Salman Bulgarskiy, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: June 29, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–16569 Filed 7–13–16; 8:45 am]

BILLING CODE 4710–AD–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36032]

Omnitrax Holdings Combined, Inc.—Acquisition of Control Exemption—Alabama & Tennessee River Railway, LLC, et al.

On May 5, 2016, OmniTRAX Holdings Combined, Inc. (OmniTRAX) filed a petition for exemption from the requirements of 49 U.S.C. 11323–25.[1] OmniTRAX seeks after-the-fact Board authority for transactions that occurred on December 31, 2015, where OmniTRAX acquired direct and exclusive control over 18 Class III railroads.[2] (Pet. 2–5.) OmniTRAX states

---

[1] Although the petition initially states that it is seeking an exemption from the requirements of only 11324 and 11325 (Pet. 2), it later specifically references 11323 as well (Pet. 6, 9).

[2] The railroads and the state(s) they operate in are as follows:

- Alabama & Tennessee River Railway, LLC: Alabama
- Alliance Terminal Railroad, LLC: Texas (not currently in operation)
- Brownsville & Rio Grande International Railway, LLC: Texas
- Chicago Rail Link, LLC: Illinois
- Fulton County Railway, LLC: Georgia
- Georgia & Florida Railway, LLC: Georgia, Florida
- Georgia Woodlands Railroad, LLC: Georgia
- Great Western Railway of Colorado, LLC: Colorado
- Illinois Railway, LLC: Illinois

that its failure to obtain proper Board authority prior to the transactions was due to inadvertent oversight. (Pet. 2.)

This proceeding is related to two pending class exemption proceedings: Docket No. FD 36018, in which Central Texas & Colorado River Railway, LLC (CTCR), a noncarrier subsidiary of OmniTRAX, seeks to acquire and operate a line of railroad, and Docket No. FD 36019, in which OmniTRAX seeks to continue in control of CTCR upon its becoming a Class III rail carrier. On May 24, 2016, OmniTRAX filed a supplement to its petition for exemption, providing additional information and a request for expedited action so as not to delay capital improvement plans for the CTCR. By decision served on May 26, 2016, the Board held the related proceedings in Docket Nos. FD 36018 and FD 36019 in abeyance pending action on OmniTRAX's petition for exemption in this proceeding. *Cent. Tex. & Colo. River Ry.—Acquis. & Operation Exemption—Line of Heart of Tex. R.R.,* FD 36018, et al. (STB served May 26, 2016).

OmniTRAX's petition for exemption will be granted. Because we are granting the petition for exemption in this proceeding, we are also reactivating the proceedings in Docket Nos. FD 36018 and FD 36019 by serving and publishing those notices in the **Federal Register**.

Background

OmniTRAX is a non-carrier holding company established to control short line railroads. (Pet. 2.) OmniTRAX states that it is owned by three separate and independent corporations, none of which possess a controlling interest in OmniTRAX.[3] (*Id.* at 5.)

Prior to the December 31, 2015 transactions in which OmniTRAX acquired direct and exclusive control of 18 Class III rail carriers, Patrick D. Broe (Broe) indirectly controlled 17 of the 18 Class III railroads. Twelve of the railroads[4] were directly controlled by OmniTRAX Holdings, LLC (OTH), which was controlled by OmniTRAX, Inc. (OTI), which was in turn controlled by Broe. In addition, Broe also indirectly controlled 5 other railroads,[5] but through other "corporate arrangements not involving OTI or OTH." (Pet. 4.)

Additionally, Broe held a non-controlling interest in the 18th railroad, Peru Industrial Railroad, LLC (PIR), an independent short line operating in Illinois. PIR connects with one of the other Class III railroads—Illinois Railway, LLC (IR)—that was acquired in the OmniTRAX transactions. These two railroads connect at Peru, Ill., but OmniTRAX asserts that the respective railroad lines do not access or serve any common industry or customer(s). OmniTRAX states that IR previously obtained exemption authority to lease and operate over PIR's lines in *Illinois Railway—Lease & Operation Exemption—Rail Line of Peru Land Acquisition 2, LLC,* FD 35886 (STB served Dec. 24, 2014). (Suppl. 6.)

As mentioned above, OmniTRAX requests expedited action because this proceeding is the limiting factor to obtaining regulatory authority in the two related proceedings in Docket Nos. FD 36018 and FD 36019. OmniTRAX states that holding those dockets in abeyance could result in delays to critical railroad physical plant improvements. (Suppl. 7.)

Discussion and Conclusions

The acquisition of control of a rail carrier (or carriers) by a person that is not a rail carrier but that controls any number of rail carriers requires approval by the Board pursuant to 49 U.S.C. 11323(a)(5). Under 10502(a), however, we must exempt a transaction or service from regulation if we find that: (1) Regulation is not necessary to carry out the rail transportation policy (RTP) of 10101; and (2) either the transaction or service is limited in scope, or regulation is not needed to protect shippers from the abuse of market power.

In this case, an exemption from the prior approval requirements of 49 U.S.C. 11323–25 is consistent with the standards of 10502. Detailed scrutiny of the proposed transactions through an application for review and approval under 11323–25 is not necessary here to carry out the RTP. Approval of the transactions at issue will result in a change in ownership of the 18 aforementioned rail carriers with no lessening of competition and will bring those railroads under the oversight of established short-line management. An exemption will promote the RTP by minimizing the need for federal regulatory control over the transactions, 10101(2); ensuring the development and continuation of a sound rail transportation system that will continue to meet the needs of the public, 10101(4); reducing the barriers to entry and exit from the rail transportation industry, 10101(7); encouraging efficient management, 10101(9); and providing for the expeditious resolution of this and the related proceedings, 10101(15). Other aspects of the RTP will not be adversely affected.

Nor is detailed scrutiny of the proposed transactions necessary to protect shippers from an abuse of market power. According to OmniTRAX, no shipper will lose access to rail service as a result of the transactions, and operations will continue as they did before OmniTRAX assumed control. (Pet. 9.) Further, OmniTRAX states that the relevant agreements related to the acquisitions contain no provision that would limit any of the 18 railroads' future interchange of traffic to or from third-party connecting carriers. (*Id.*) Although PIR connects with IR, OmniTRAX states that their lines do not access or serve any common industry or customers. In addition, OmniTRAX states that "PIR's only outlet to the balance of the interstate railroad network is via its connection to IR," that PIR and its customers would continue to rely upon intermediate IR service to reach line-haul carriers. (Suppl. 6.) Accordingly, based on the record, these transactions do not appear to shift or consolidate market power; therefore, we do not find that regulation is necessary to protect shippers from the abuse of market power.[6]

---

* Kettle Falls International Railway, LLC: Washington (and British Columbia, Canada)

* Manufacturers' Junction Railway, LLC: Illinois

+ Nebraska, Kansas & Colorado Railway, LLC: Nebraska, Kansas, Colorado

* Newburgh & South Shore Railroad, LLC: Ohio

* Northern Ohio & Western Railway, LLC: Ohio

* Panhandle Northern Railroad, LLC: Texas Peru Industrial Railroad, LLC: Illinois

+ Sand Springs Railway Company: Oklahoma

+ Stockton Terminal and Eastern Railroad: California (Pet. 3.)

[3] OmniTRAX states that "no individual or corporate entity possesses a direct or indirect controlling interest in OmniTRAX at this time." (Pet. 5.) Control is a fact-intensive determination, and this decision makes no finding based on this statement by OmniTRAX. If, as one example, an individual directly or indirectly controlled two of the three parent corporations of OmniTRAX, that individual would also need Board authority.

[4] These twelve carriers are denoted with an asterisk in footnote 3.

[5] These five carriers are denoted with a plus symbol in footnote 3. Although the petition did not provide details of the relationship between Broe and these carriers, in *Patrick D. Broe—Acquisition of Control Exemption—Stockton Terminal & Eastern Railroad,* FD 35525 (STB served July 15, 2011), Broe obtained authority to acquire indirect control via ST&E Holdings, Inc., of one of the five carriers, the Stockton Terminal & Eastern Railroad Company. Later, in *Patrick D. Broe—Acquisition of Control Exemption—Sand Springs Railway,* FD 35829 (STB served June 12, 2014), Broe obtained authority to acquire indirect control via Sand Springs Holdings, LLC, of another of the five carriers, the Sand Springs Railway Company. In Broe's 2014 filings with the Board in the latter docket, he noted that he controls BNS Holdings, Inc., a noncarrier that indirectly controlled the three remaining carriers. Broe Notice of Exemption 4, *Patrick D. Broe—Acquis. of Control Exemption—Sand Springs Ry.,* FD 35829.

[6] As there is no evidence that regulation is needed to protect shippers from the abuse of market power,

Continued

Under 49 U.S.C. 10502(g), we may not use our exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. The Board, however, is not required to impose labor protective conditions when only Class III rail carriers are involved in a transaction that falls under 49 U.S.C. 11324–25, as is the case here. 49 U.S.C. 11326(c).

These transactions are categorically excluded from environmental review under 49 CFR. 1105.6(c)(2)(i) because they will not result in any significant change in carrier operations. Similarly, the transactions are exempt from the historic reporting requirements under 49 CFR. 1105.8(b)(3) because they will not substantially change the level of maintenance of railroad properties.

As indicated, OmniTRAX has requested expedited action to avoid delays to critical railroad physical plant improvements. We find OmniTRAX's request to be reasonable. We will grant the exemption and the exemption will be effective immediately.

It is ordered:

1. Under 49 U.S.C. 10502, the Board exempts the above-described transactions from the prior approval requirements of 11323–25.
2. Notice will be published in the **Federal Register**.
3. This exemption will be effective on July 14, 2016.

Decided: July 11, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2016–16671 Filed 7–13–16; 8:45 am]

BILLING CODE 4915–01–P

---

we do not need to determine whether the transaction is limited in scope. *See* 49 U.S.C. 10502(a).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36018]

Central Texas & Colorado River Railway, LLC—Acquisition and Operation Exemption—Line of Heart of Texas Railroad, L.P.

Central Texas & Colorado River Railway, LLC (CTCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Heart of Texas Railroad, L.P. (HTR), and to operate a line of railroad extending between Lometa, Tex., and Brady, Tex. (the Brady Line). CTCR will acquire the 67.5-mile Brady Line, which connects with a BNSF Railway Company line at milepost 0.0 in Lometa and continues to the end of the track in Brady, pursuant to a purchase and sale agreement.

CTCR states that HTR has operated the Brady Line since 2013 when HTR acquired the Brady Line from the bankruptcy estate of the prior owner.[1]

CTCR is a subsidiary of OmniTRAX Holdings Combined, Inc. (OmniTRAX). This transaction is related to a concurrently filed verified notice of exemption in *OmniTRAX Holdings Combined, Inc.—Continuance in Control Exemption—Central Texas & Colorado River Railway,* Docket No. FD 36019, in which OmniTRAX seeks Board approval under 49 CFR 1180.2(d)(2) to continue in control of CTCR upon CTCR's becoming a Class III rail carrier. OmniTRAX currently controls 18 Class III rail carriers (OmniTRAX Railroads) in the United States.[2]

This exemption is effective July 28, 2016.

CTCR certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier and does not exceed $5 million. CTCR also certifies that the purchase and sale agreement between HTR and CTCR does not involve any provision limiting CTCR's future interchange of traffic with a third-party connecting carrier.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than July 21, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36018, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on William C. Sippel, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606.

According to CTCR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: July 11, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–16673 Filed 7–13–16; 8:45 am]

BILLING CODE 4915–01–P

---

[1] *See Heart of Tex. R.R.—Acquis. & Operation Exemption—Gulf Colo. & San Saba Ry.*, FD 35710 (STB served Jan. 4, 2013).

[2] In its verified notice filed in Docket No FD. 36019, OmniTRAX explains that in preparing the two related class exemption filings, it was discovered that OmniTRAX had acquired direct and exclusive control of the 18 OmniTRAX Railroads on December 31, 2015. It states that it inadvertently did not seek advanced authority to engage in the acquisition of control, "in part because of the preexisting close association among all of the involved carriers and their largely common short line heritage." On May 5, 2016, OmniTRAX filed a petition for exemption in Docket No. FD 36032 to seek the requisite authority to acquire control of the OmniTRAX Railroads, and by decision served on May 26, 2016, the Board held the notice of exemption proceedings in abeyance pending a ruling on the petition. The Board granted the petition in a decision served July 14, 2016, and therefore is removing this proceeding from abeyance and publishing this notice.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36019]

OmniTRAX Holdings Combined, Inc.—Continuance in Control Exemption—Central Texas & Colorado River Railway, LLC

OmniTRAX Holdings Combined, Inc. (OmniTRAX) has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of Central Texas & Colorado River Railway, LLC (CTCR), a noncarrier, upon CTCR's becoming a Class III rail carrier. CTCR is a wholly owned subsidiary of OmniTRAX.

This transaction is related to a concurrently filed verified notice of exemption in *Central Texas & Colorado River Railway—Acquisition & Operation Exemption—Line of Heart of Texas Railroad,* Docket No. FD 36018, in which CTCR seeks Board approval under 49 CFR 1150.31 to acquire and operate a line of railroad extending 67.5 miles from Lometa, Tex., to the end of the track at Brady, Tex. (the Brady Line).

OmniTRAX is a noncarrier holding company that controls 18 Class III rail carrier subsidiaries (the OmniTRAX Railroads) subject to the Board's jurisdiction.[1] This transaction will permit it to exercise common control of these entities and CTCR once CTCR acquires the Brady Line.

---

[1] In its verified notice, OmniTRAX explains that in preparing the two related class exemption filings, it was discovered that OmniTRAX had acquired direct and exclusive control of the 18 OmniTRAX Railroads on December 31, 2015. It states that it inadvertently did not seek advanced authority to engage in the acquisition of control, "in part because of the preexisting close association among all of the involved carriers and their largely common short line heritage." On May 5, 2016, OmniTRAX filed a petition for exemption in Docket No. FD 36032 to seek the requisite authority to acquire control of the OmniTRAX Railroads, and by decision served on May 26, 2016, the Board held the notice of exemption proceedings in abeyance

The exemption will become effective July 28, 2016.

OmniTRAX represents that: (1) The rail line to be acquired and operated by CTCR does not connect with the lines of any of the OmniTRAX Railroads; (2) the continuance in control transaction is not part of a series of anticipated transactions that would result in such a connection; and (3) the proposed transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than July 21, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36019, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on William C. Sippel, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606. Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: July 11, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–16674 Filed 7–13–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. 2, 10(a)(2), that a meeting will be held at the Hay-Adams Hotel, 16th Street and Pennsylvania Avenue NW., Washington, DC on August 2, 2016 at 11:30 a.m. of the following debt management advisory committee: Treasury Borrowing Advisory Committee of the Securities Industry and Financial Markets Association.

The agenda for the meeting provides for a charge by the Secretary of the Treasury or his designate that the Committee discuss particular issues and conduct a working session. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. 2, 10(d) and Public Law 103–202, 202(c)(1)(B) (31 U.S.C. 3121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. 2, 10(d) and vested in me by Treasury Department Order No. 101–05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103–202,202(c)(1)(B). Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B).

In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. 2, 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the Committee, premature disclosure of the Committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

Treasury staff will provide a technical briefing to the press on the day before the Committee meeting, following the release of a statement of economic conditions and financing estimates. This briefing will give the press an opportunity to ask questions about financing projections. The day after the Committee meeting, Treasury will release the minutes of the meeting, any charts that were discussed at the meeting, and the Committee's report to the Secretary.

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency official who may be contacted for additional information is Fred Pietrangeli, Director for Office of Debt Management (202) 622–1876.

Dated: July 7, 2016.

Fred Pietrangeli,

Director, Office of Debt Management.

[FR Doc. 2016–16509 Filed 7–13–16; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of amendment of system of records.

SUMMARY: As required by the Privacy Act of 1974 (5 U.S.C. 552a(e)(4)), notice is hereby given that the Department of Veterans Affairs (VA) is amending the system of records entitled "Enrollment and Eligibility Records-VA" (147VA16) as set forth in 73 FR 15847. VA is amending the system of records by revising the System Number, System Location, Categories of Individuals Covered by the System, Category of Records in the System, Authority for Maintenance of the System, Purpose, Routine Uses of Records Maintained in the System, Storage, Safeguards, Retention and Disposal, and Record Source Category. VA is republishing the system notice in its entirety.

DATES: Comments on this new system of records must be received no later than August 15, 2016. If no public comment is received during the period allowed for comment or unless otherwise

---

pending a ruling on the petition. The Board granted the petition in a decision served July 14, 2016, and therefore is removing this proceeding from abeyance and publishing this notice.

published in the **Federal Register** by VA, the new system will become effective August 15, 2016.

ADDRESSES: Written comments concerning the amended system of records may be submitted through *www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration (VHA) Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; telephone (704) 245–2492.

SUPPLEMENTARY INFORMATION: The System Number is changed from 147VA16 to 147VA10NF1 to reflect the current organizational alignment.

The System Location is being amended to remove Austin Automation Center (AAC) and replace it with Austin Information Technology Center (AITC); and 24VA19 is being removed and replaced with 24VA10P2. Also, Veteran Identification Card (VIC) National Card Management Directory (NCMD) located at the Hines, Illinois, and Silver Spring, Maryland VA facilities is being removed and replaced with Veteran Health Identification Card (VHIC) located at the AITC and 3M Cogent, Inc.

The Category of Individuals Covered by the System is being amended to include Veterans and caregivers inquiring about, applying for and participating in the Program of Comprehensive Assistance for Family Caregivers and the Program of General Caregiver Support Services established by the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163, signed into law on May 5, 2010, as well as individuals who call into the VA's Caregiver Support Line.

The Category of Records in the System is being amended to add Member ID number—which is Department of Defense's Electronic Data Interchange Personal Identifier (EDIPI), Plan ID, special awards and Branch of Service. The Caregiver database that tracks these program participants includes, but is not limited to: The Veteran and/or caregiver(s) name, Social Security number, gender, age, date of birth, address, phone number, and email address; VA eligibility related information, such as service connection, DD 214, "Certification of Release or Discharge from Active Duty", Line of Duty documentation, and stipend payment information; written correspondence; VA Form 10–10CG, "Application for Comprehensive Assistance for Family Caregiver Program"; and correspondence with Caregiver Support Line, including referral information and VA staff remarks.

The Authority for Maintenance of the System is being amended to add Title 28 U.S.C. and 38 U.S.C. 1720G.

The Purpose is being updated to include VA's Caregiver Support Program and providing enrolled Veterans with customized Veterans Health Benefits Handbooks.

The Routine Uses of Records Maintained in the System has been amended by adding Routine Use #15 which states, "VA may disclose the name and Veteran Health Identification Card image of a missing patient from a VA health care facility to local law enforcement for the purpose of assisting in locating the missing patient." VA needs to locate missing patients quickly for their safety and enlisting the assistance of local law enforcement is crucial to being able to find patients as quick as possible.

The Storage is being amended to remove NCMD databases and replace it with 3M Cogent, Inc. databases.

The Safeguard section is being amended to remove Silver Spring and Hines databases and replace it with 3M Cogent, Inc. AAC is being replaced with AITC and VIC is being replaced with VHIC.

The Retention and Disposal is being amended to remove the language that Regardless of the record medium, all records are disposed of in accordance with the records retention standards approved by the Archivist of the United States, NARA, and published in the VHA Records Control Schedule 10–1. This section is being replaced with per Records Control Schedule (RCS) 10–1 May of 2016; Use disposition schedule 1250.1.b Health Eligibility Center (HEC) Records, Optical Disks or Other Electronic Medium will be temporarily deleted when all phase of the Veteran's appeal rights have ended (ten years after the income year for which the means test verification was conducted) (N1–15–98–3, item 2). All Ad-Hoc reports created as part of this system shall be managed per National Archives and Records Administration (NARA) approved General Record Schedule (GRS) 3.2 Items 030, Ad-Hoc reports.

The Record Source Category is being amended to replace 24VA19 with 24VA10P2; 79VA19 with 79VA10P2; and 89VA16 with 89VA10NB.

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, approved this document on June 30, 2016, for publication.

Dated: July 6, 2016.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

147VA10NF1

SYSTEM NAME:

Enrollment and Eligibility Records-VA.

SYSTEM LOCATION:

Records are maintained at the Health Eligibility Center (HEC) in Atlanta, Georgia; the Austin Information Technology Center (AITC) in Austin, Texas; at each VA health care facility as described in the VA system of records entitled "Patient Medical Records-VA" (24VA10P2); and at the Veteran Health Identification Card (VHIC) located at the AITC and 3M Cogent, Inc. Electronic and magnetic records are also stored at contracted facilities for storage and back-up purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 28 U.S.C., title 38, U.S.C., sections 501(a), 1705, 1710, 1720G, 1722, and 5317.

PURPOSE(S):

Information in this system of records is used to establish and maintain applicants' records necessary to support the delivery of health care benefits; establish applicants' eligibility for VA health care benefits; VA's Caregiver Support Program; operate an annual enrollment system; provide eligible Veterans with an identification card;

collect from an applicant's health insurance provider for care of their nonservice-connected conditions; provide educational materials related to VA health care benefits, such as the customized Veterans Health Benefits Handbook, respond to Veteran and non-Veteran inquiries related to VA health care benefits, and compile management reports.

CATEGORIES OF INDIVIDUALS COVERED BY THIS SYSTEM:

The records contain information on individuals who have applied for or who have received VA health care benefits under title 38 U.S.C., chapter 17. The records also include Veterans and caregivers inquiring about, applying for and participating in the Program of Comprehensive Assistance for Family Caregivers and the Program of General Caregiver Support Services established by the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163, signed into law on May 5, 2010, as well as individuals who call into VA's Caregiver Support Line, Veterans, their spouses and dependents as provided for in other provisions of title 38 U.S.C.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in this system may include: Medical benefit applications; eligibility and enrollment information, including information obtained from Veterans Benefits Administration's automated records, such as the "Compensation, Pension, Education and Rehabilitation Records-VA" (58VA21/22), and VHIC information including applicant's name, address(es), date of birth, Member ID number—which is Department of Defense's Electronic Data Interchange Personal Identifier (EDIPI), Plan ID, special awards and Branch of Service, Internal Control Number (ICN), applicant's image, preferred facility and facility requesting a VHIC, names, addresses and phone numbers of persons to contact in the event of a medical emergency, family information including spouse and dependent(s) name(s), address(es) and Social Security number; applicant and spouse's employment information, including occupation, employer(s) name(s) and address(es); financial information concerning the applicant and the applicant's spouse including family income, assets, expenses, debts; third party health plan contract information, including health insurance carrier name and address, policy number and time period covered by policy; facility location(s) where treatment is provided; type of treatment provided (*i.e.,* inpatient or outpatient); information about the applicant's military service (*e.g.,* dates of active duty service, dates and branch of service, and character of discharge, combat service dates and locations, military decorations, POW status and military service experience including exposures to toxic substances); information about the applicant's eligibility for VA compensation or pension benefits, and the applicant's enrollment status and enrollment priority group. These records also include, but are not limited to, individual correspondence provided to the HEC by Veterans, their family members and Veterans' representatives, such as Veteran Service Officers (VSO); copies of death certificates; DD Form 214, "Certificate of Release or Discharge from Active Duty"; disability award letters; VA and other pension applications; VA Form 10–10EZ, "Application for Health Benefits"; VA Form 10–10EZR, "Health Benefits Renewal"; VA Form 10–10EC, "Application for Extended Care Services"; and workers compensation forms. The Caregiver database that tracks these program participants includes, but is not limited to: the Veteran and/or caregiver(s) name, Social Security number, gender, age, date of birth, address, phone number, and email address; VA eligibility related information, such as service connection, DD 214, "Certification of Release or Discharge from Active Duty", Line of Duty documentation, and stipend payment information; written correspondence; VA Form 10–10CG, "Application for Comprehensive Assistance for Family Caregiver Program"; and correspondence with Caregiver Support Line, including referral information and VA staff remarks.

RECORD SOURCE CATEGORIES:

Information in the systems of records may be provided by the applicant; applicant's spouse or other family members or accredited representatives or friends; health insurance carriers; other Federal agencies; "Patient Medical Records-VA" (24VA10P2) system of records; "Veterans Health Information System and Technology Architecture (VistA) Records-VA" (79VA10P2); "Income Verification Records-VA" (89VA10NB); and Veterans Benefits Administration automated record systems, including "Veterans and Beneficiaries Identification and Records Location Subsystem-VA" (38VA23) and the "Compensation, Pension, Education and Rehabilitation Records-VA" (58VA21/22).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164 (*i.e.,* individually identifiable health information), that information cannot be disclosed under a routine use unless there is also specific regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

1. VA may disclose information from this system of records, as deemed necessary and proper, to named individuals serving as accredited service organization representatives and other individuals named as approved agents or attorneys for a documented purpose and period of time, to aid beneficiaries in the preparation and presentation of their cases during the verification and/or due process procedures and in the presentation and prosecution of claims under laws administered by VA.

2. VA may disclose on its own initiative any information in this system, except the names and home addresses of Veterans and their dependents, which is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, State, local, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order. On its own initiative, VA may also disclose the names and addresses of Veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

3. VA may disclose information from this system of records to private attorneys representing Veterans rated incompetent in conjunction with issuance of Certificates of Incompetence, in the course of presenting evidence to a court, magistrate or administrative tribunal, in matters of guardianship, inquests and commitments; and to probation and parole officers in connection with court required duties.

4. VA may disclose information to a VA Federal fiduciary or a guardian ad litem in relation to his or her representation of a Veteran only to the extent necessary to fulfill the duties of the VA Federal fiduciary or the guardian ad litem.

5. VA may disclose information to attorneys, insurance companies, employers, third parties liable or potentially liable under health plan contracts, and to courts, boards, or commissions, but only to the extent necessary to aid VA in the preparation, presentation, and prosecution of claims authorized under Federal, State, or local laws, and regulations promulgated thereunder.

6. VA may disclose information in this system of records to the Department of Justice (DoJ), either on VA's initiative or in response to DoJ's request for the information, after either VA or DoJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that disclosure of the records to the DoJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

7. VA may disclose information to the NARA and General Services Administration in records management inspections conducted under authority of title 44 U.S.C.

8. VA may disclose information for the purposes identified below to a third party, except consumer reporting agencies, in connection with any proceeding for the collection of an amount owed to the United States by virtue of a person's participation in any benefit program administered by VA. Information may be disclosed under this routine use only to the extent that it is reasonably necessary for the following purposes: (a) To assist VA in the collection of costs of services provided individuals not entitled to such services, (b) to initiate civil or criminal legal actions for collecting amounts owed to the United States, and (c) for prosecuting individuals who willfully or fraudulently obtained or seek to obtain title 38 medical benefits. This disclosure is consistent with 38 U.S.C. 5701(b)(6).

9. VA may disclose information such as the name and address of a Veteran or other information as is reasonably necessary to identify such Veteran, and any information concerning the Veteran's indebtedness to the United States by virtue of the person's participation in a benefits program administered by VA, to a consumer reporting agency for purposes of assisting in the collection of such indebtedness, provided that the provisions of 38 U.S.C. 5701(g)(4) have been met.

10. VA may disclose information to individuals, organizations, private or public agencies, or other entities with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA in order for the individual or entity with whom VA has an agreement or contract to perform the services of the contract or agreement. This routine use includes disclosures by the individual or entity performing the service for VA to any secondary individual or entity to perform an activity that is necessary for the individual or entity with whom VA has a contract or agreement to provide the service to VA.

11. VA may disclose information from the record of an individual who is covered by a system of records to a member of Congress, or a staff person acting for the member, when the member or staff person requests the record on behalf of and at the written request of the individual.

12. VA may disclose information to other Federal agencies to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

13. VA may, on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosure is required by the Memorandum from the Office of Management and Budget (M–07–16), dated May 22, 2007, of all systems of records of all Federal agencies. This routine use also permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

14. Identifying information, including Social Security number of Veterans, spouse(s) of Veterans, and dependents of Veterans, may be disclosed to other Federal agencies for purposes of conducting computer matches, to obtain information to determine or verify eligibility of Veterans who are receiving VA medical care under relevant sections of title 38 U.S.C.

15. VA may disclose the name and VHIC image of a missing patient from a VA health care facility to local law enforcement for the purpose of assisting in locating the missing patient.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained on magnetic tape, magnetic disk, optical disk and paper at the HEC, VHIC databases, VA medical centers, the 3M Cogent, Inc. databases, AITC, contract facilities, and at Federal Record Centers. In most cases, copies of back-up computer files are maintained at off-site locations and/or agencies with whom VA has a contract or agreement to perform such services, as VA may deem practicable.

POLICIES AND PRACTICES FOR RETRIEVABILITY OF RECORDS:

Records are retrieved by name, and/or Social Security number, ICN, military service number, claim folder number, correspondence tracking number, internal record number, facility number, or other assigned identifiers of the individuals on whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Per RCS10–1 May of 2016; use disposition schedule 1250.1.b HEC Records, Optical Disks or Other Electronic Medium will be temporarily deleted when all phase of the Veteran's appeal rights have ended (ten years after the income year for which the means test verification was conducted) (N1–15–98–3, item 2). All Ad-Hoc reports created as part of this system shall be managed per NARA approved GRS 3.2 Items 030, Ad-Hoc reports.

PHYSICAL, PROCEDURAL, AND ADMINISTRATIVE SAFEGUARDS:

1. Data transmissions between VA health care facilities, the HEC, the AITC,

3M Cogent, Inc. databases are accomplished using the Department's secure wide area network. The software programs automatically flag records or events for transmission based upon functional requirements. Server jobs at each facility run continuously to check for data to be transmitted and/or incoming data which needs to be parsed to files on the receiving end. All messages containing data transmissions include header information that is used for validation purposes. The recipients of the messages are controlled and/or assigned to the mail group based on their role or position. Consistency checks in the software are used to validate the transmission and electronic acknowledgment messages are returned to the sending application. VA's Office of Cyber Security has oversight responsibility for planning and implementing computer security.

2. Working spaces and record storage areas at HEC, AITC, and the VHIC processing locations are secured during all business hours, as well as during non-business hours. All entrance doors require an electronic pass card, for entry when unlocked, and entry doors are locked outside normal business hours. Visitors to the HEC are required to present identification, sign-in at a specified location, and are issued a pass card that restricts access to non-sensitive areas. Visitors to the HEC are escorted by staff through restricted areas. At the end of the visit, visitors are required to turn in their badge. The building is equipped with an intrusion alarm system, which is activated during non-business hours. This alarm system is monitored by a private security service vendor. The office space occupied by employees with access to Veteran records is secured with an electronic locking system, which requires a card for entry and exit of that office space. Access to the AITC is generally restricted to AITC staff, VA Central Office employees, custodial personnel, Federal Protective Service and authorized operational personnel through electronic locking devices. All other persons gaining access to the computer rooms are escorted.

3. Access to the VHIC contractor secured work areas is also controlled by electronic entry devices, which require a card and manual input for entry and exit of the production space. The VHIC contractor's building is also equipped with an intrusion alarm system and a security service vendor monitors the system.

4. Contract employees are required to sign a Business Associates Agreement as required by the HIPAA Privacy Rule as acknowledgement of mandatory provisions regarding the use and disclosure of protected health information. Employee and contractor access is deactivated when no longer required for official duties or upon termination of employment. Recurring monitors are in place to ensure compliance with nationally and locally established security measures.

5. Beneficiary's enrollment and eligibility information is transmitted from the Enrollment and Eligibility information system to VA health care facilities over the Department's secure computerized electronic communications system.

6. Only specific key staff have authorized access to the computer room. Programmer access to the information systems is restricted only to staff whose official duties require that level of access.

7. On-line data reside on magnetic media in the HEC and AITC computer rooms that are highly secured. Backup media are stored in the computer room within the same building and only information system staff and designated management staff have access to the computer room. On a weekly basis, backup media are stored in off-site storage by a media storage vendor. The vendor picks up and returns the media in a locked storage container; vendor personnel do not have key access to the locked container. The AITC has established a backup plan for the Enrollment system as part of a required Certification and Accreditation of the information system.

8. Any sensitive information that may be downloaded to personal computers or printed to hard copy format is provided the same level of security as the electronic records. All paper documents and informal notations containing sensitive data are shredded prior to disposal. All magnetic media (primary computer system) and personal computer disks are degaussed prior to disposal or release off-site for repair. The VHIC contractor destroys all Veteran identification data 30 days after the VHIC card has been mailed to the Veteran in accordance with contractual requirements.

9. All new HEC employees receive initial information security and privacy training; refresher training is provided to all employees on an annual basis. The HEC's Information Security Officer performs an annual information security audit and periodic reviews to ensure security of the system. This annual audit includes the primary computer information system, the telecommunication system, and local area networks. Additionally, the Internal Revenue Service performs periodic on-site inspections to ensure the appropriate level of security is maintained for Federal tax data.

10. Identification codes and codes used to access Enrollment and Eligibility information systems and records systems, as well as security profiles and possible security violations, are maintained on magnetic media in a secure environment at the Center. For contingency purposes, database backups on removable magnetic media are stored off-site by a licensed and bonded media storage vendor.

11. Contractors, subcontractors, and other users of the Enrollment and Eligibility Records systems will adhere to the same safeguards and security requirements to which HEC staff must comply.

ACCESS:

1. In accordance with national and locally established data security procedures, access to enrollment information databases (HEC Legacy system and the Enrollment Database) is controlled by unique entry codes (access and verification codes). The user's verification code is automatically set to be changed every 90 days. User access to data is controlled by role-based access as determined necessary by supervisory and information security staff as well as by management of option menus available to the employee. Determination of such access is based upon the role or position of the employee and functionality necessary to perform the employee's assigned duties.

2. On an annual basis, employees are required to sign a computer access agreement acknowledging their understanding of confidentiality requirements. In addition, all employees receive annual privacy awareness and information security training. Access to electronic records is deactivated when no longer required for official duties. Recurring monitors are in place to ensure compliance with nationally and locally established security measures.

3. User access to the VHIC database utilizes the national NT network authentication infrastructure. The external VHIC vendor utilizes the One-VA Virtual Private Network secured connection for access to VHIC records.

4. Strict control measures are enforced to ensure that access to and disclosure from all records is limited to VA and the contractor's employees whose official duties warrant access to those files.

5. As required by the provisions of the Health Insurance Portability and Accountability ACT (HIPAA) Privacy Rule, 45 CFR parts 160 and 164, access to records by HEC employees is

classified under functional category "Eligibility and Enrollment Staff."

SYSTEM MANAGER(S) AND ADDRESSES:

Official responsible for policies and procedures: Chief Business Officer (10NB), VA Central Office, 1722 I Street NW., Washington, DC 20420. Official maintaining the system: Director, Health Eligibility Center, 2957 Clairmont Road, Atlanta, GA 30329.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of Enrollment and Eligibility Records may write to the Director, Health Eligibility Center, 2957 Clairmont Road, Atlanta, GA 30329.

CONTESTING RECORD PROCEDURES:

(See Record Access procedures above).

NOTIFICATION PROCEDURE:

Any individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the Health Eligibility Center. All inquiries must reasonably identify the records requested. Inquiries should include the individual's full name, Social Security number, military service number, claim folder number and return address.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

[FR Doc. 2016–16640 Filed 7–13–16; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 482, *et al.*
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 482, 486, 488, and 495

[CMS–1656–P]

RIN 0938–AS82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2017 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, in this proposed rule, we are proposing to make changes to tolerance thresholds for clinical outcomes for solid organ transplant programs; to Organ Procurement Organizations (OPOs) definitions, outcome measures, and organ transport documentation; and to the Medicare and Medicaid Electronic Health Record Incentive Programs. We also are proposing to remove the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program. In addition, we are proposing to implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider.

DATES: *Comment period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 6, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1656–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "submit a comment" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1656–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1656–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact Carol Schwartz at (410) 786–0576.

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel at (410) 786–0237.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at (410) 786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur at (410) 786–8819.

Blood and Blood Products, contact Lela Strong at (410) 786–3213.

Cancer Hospital Payments, contact David Rice at (410) 786–6004.

Chronic Care Management (CCM) Hospital Services, contact Twi Jackson at (410) 786–1159.

CPT and Level II Alphanumeric HCPCS Codes—Process for Requesting Comments, contact Marjorie Baldo at (410) 786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver at (410) 786–9379.

Composite APCs (Extended Assessment and Management, Low Dose Brachytherapy, Multiple Imaging), contact Twi Jackson at (410) 786–1159.

Comprehensive APCs, contact Lela Strong at (410) 786–3213.

Hospital Observation Services, contact Twi Jackson at (410) 786–1159.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Elizabeth Bainger at (410) 786–0529.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur at (410) 786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at (410) 786–1159.

Hospital Value-Based Purchasing (VBP) Program, contact Grace Im at (410) 786–0700.

Inpatient Only Procedures List, contact Lela Strong at (410) 786–3213.

Medicare Electronic Health Record (EHR) Incentive Program, contact Kathleen Johnson at (410) 786–3295 or Steven Johnson at (410) 786–3332.

New Technology Intraocular Lenses (NTIOLs), contact Elisabeth Daniel at (410) 786–0237.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson at (410) 786–1159.

OPPS Brachytherapy, contact Elisabeth Daniel at (410) 786–0237.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact David Rice at (410) 786–6004 or Erick Chuang at (410) 786–1816.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Twi Jackson at (410) 786–1159.

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo at (410) 786–4617.

OPPS Packaged Items/Services, contact Lela Strong at (410) 786–3213.

OPPS Pass-Through Devices and New Technology Procedures/Services, contact Carol Schwartz at (410) 786–0576.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova at (410) 786–2682.

Organ Procurement Organization (OPO) Reporting and Communication, contact Peggye Wilkerson at (410) 786–4857 or Melissa Rice at (410) 786–3270.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact Marissa Kellam at (410) 786–3012 or Katherine Lucas at (410) 786–7723.

Rural Hospital Payments, contact David Rice at (410) 786–6004.

Section 603 of the Bipartisan Budget Act of 2015 (Off-Campus Departments of a Provider), contact David Rice at (410) 786–6004 or Elisabeth Daniel at (410) 786–0237.

Transplant Enforcement, contact Paula DiStabile at (410) 786–3039 or Caecilia Blondiaux at (410) 786–2190.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo at (410) 786–4617.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html.*

Alphabetical List of Acronyms Appearing in This Federal Register Document

ACOT	Advisory Committee on Organ Transplantation
AHA	American Hospital Association
AMA	American Medical Association
AMI	Acute myocardial infarction
APC	Ambulatory Payment Classification
APU	Annual payment update
ASC	Ambulatory surgical center
ASCQR	Ambulatory Surgical Center Quality Reporting
ASP	Average sales price
AUC	Appropriate use criteria
AWP	Average wholesale price
BBA	Balanced Budget Act of 1997, Public Law 105–33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS	Bureau of Labor Statistics
CAH	Critical access hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CAP	Competitive Acquisition Program
C–APC	Comprehensive Ambulatory Payment Classification
CASPER	Certification and Survey Provider Enhanced Reporting
CAUTI	Catheter-associated urinary tract infection
CBSA	Core-Based Statistical Area
CCM	Chronic care management
CCN	CMS Certification Number
CCR	Cost-to-charge ratio
CDC	Centers for Disease Control and Prevention
CED	Coverage with Evidence Development
CERT	Comprehensive Error Rate Testing
CfC	Conditions of coverage
CFR	Code of Federal Regulations
CI	Comment indicator
CLABSI	Central Line [Catheter] Associated Blood Stream Infection
CLFS	Clinical Laboratory Fee Schedule
CMHC	Community mental health center
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of participation
CPI–U	Consumer Price Index for All Urban Consumers
CPT	Current Procedural Terminology (copyrighted by the American Medical Association)
CR	Change request
CRC	Colorectal cancer
CSAC	Consensus Standards Approval Committee
CT	Computed tomography
CV	Coefficient of variation
CY	Calendar year
DFO	Designated Federal Official
DIR	Direct or indirect remuneration
DME	Durable medical equipment
DMEPOS	Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
DRA	Deficit Reduction Act of 2005, Public Law 109–171
DSH	Disproportionate share hospital
EACH	Essential access community hospital
EAM	Extended assessment and management
ECD	Expanded criteria donor
EBRT	External beam radiotherapy
ECG	Electrocardiogram
ED	Emergency department
EDTC	Emergency department transfer communication
EHR	Electronic health record
E/M	Evaluation and management
ESRD	End-stage renal disease
ESRD QIP	End-Stage Renal Disease Quality Improvement Program

FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FTE Full-time equivalent
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
GME Graduate medical education
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCP Health care personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HCUP Healthcare Cost and Utilization Project
HEU Highly enriched uranium
HH QRP Home Health Quality Reporting Program
HHS Department of Health and Human Services
HIE Health information exchange
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
HOP QDRP Hospital Outpatient Quality Data Reporting Program
HPMS Health Plan Management System
IBD Inflammatory bowel disease
ICC Interclass correlation coefficient
ICD Implantable cardioverter defibrillator
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10 International Classification of Diseases, Tenth Revision
ICH In-center hemodialysis
ICR Information collection requirement
IME Indirect medical education
IDTF Independent diagnostic testing facility
IGI IHS Global Insight, Inc.
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IORT Intraoperative radiation treatment
IPFQR Inpatient Psychiatric Facility Quality Reporting
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IT Information technology
LCD Local coverage determination
LDR Low dose rate
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MEG Magnetoencephalography
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA-TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MLR Medical loss ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
MR Medical review
MRA Magnetic resonance angiography
MRgFUS Magnetic Resonance Image Guided Focused Ultrasound
MRI Magnetic resonance imaging
MRSA Methicillin-Resistant Staphylococcus Aures
MS–DRG Medicare severity diagnosis-related group
MSIS Medicaid Statistical Information System
MUC Measure under consideration
NCCI National Correct Coding Initiative
NEMA National Electrical Manufacturers Association
NHSN National Healthcare Safety Network
NOTA National Organ and Transplantation Act
NOS Not otherwise specified
NPI National Provider Identifier
NPWT Negative Pressure Wound Therapy
NQF National Quality Forum
NQS National Quality Strategy
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
O/E Observed to expected event
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPD [Hospital] Outpatient Department
OPO Organ Procurement Organization
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OPTN Organ Procurement and Transplantation Network
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCHQR PPS-Exempt Cancer Hospital Quality Reporting
PCR Payment-to-cost ratio
PDC Per day cost
PDE Prescription Drug Event
PE Practice expense
PEPPER Program Evaluation Payment Patterns Electronic Report
PHP Partial hospitalization program
PHS Public Health Service Act, Public Law 96–88
PN Pneumonia
POS Place of service
PPI Producer Price Index
PPS Prospective payment system
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RTI Research Triangle Institute, International
RVU Relative value unit
SAD Self-administered drug
SAMS Secure Access Management Services
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SES Socioeconomic status
SI Status indicator
SIA Systems Improvement Agreement
SIR Standardized infection ratio
SNF Skilled nursing facility
SRS Stereotactic radiosurgery
SRTR Scientific Registry of Transplant Recipients
SSA Social Security Administration
SSI Surgical site infection
TEP Technical Expert Panel
TIP Transprostatic implant procedure
TOPs Transitional Outpatient Payments
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
WAC Wholesale acquisition cost

Table of Contents

I. Summary and Background
  A. Executive Summary of This Document
  1. Purpose
  2. Summary of the Major Provisions
  3. Summary of Costs and Benefits
  B. Legislative and Regulatory Authority for the Hospital OPPS
  C. Excluded OPPS Services and Hospitals
  D. Prior Rulemaking
  E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)
  1. Authority of the Panel
  2. Establishment of the Panel
  3. Panel Meetings and Organizational Structure
  F. Public Comments Received in Response to CY 2016 OPPS/ASC Final Rule With Comment Period
II. Proposed Updates Affecting OPPS Payments
  A. Proposed Recalibration of APC Relative Payment Weights
  1. Database Construction
  a. Database Source and Methodology
  b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)
  2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting
  a. Recommendations of the Panel Regarding Data Development
  b. Proposed Calculation of Single Procedure APC Criteria-Based Costs
  (1) Blood and Blood Products
  (2) Brachytherapy Sources
  c. Proposed Comprehensive APCs (C–APCs) for CY 2017
  (1) Background
  (2) Proposed C–APCs for CY 2017
  (a) Proposed Additional CY 2017 C–APCs

(b) Proposed New Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) C–APC
d. Proposed Calculation of Composite APC Criteria-Based Costs
(1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC
(2) Mental Health Services Composite APC
(3) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)
3. Proposed Changes to Packaged Items and Services
a. Background and Rationale for Packaging in the OPPS
b. Proposed Clinical Diagnostic Laboratory Test Packaging Policy
(1) Background
(2) Proposed "Unrelated" Laboratory Test Exception
(3) Proposed Molecular Pathology Test Exception
c. Conditional Packaging Status Indicators "Q1" and "Q2"
(1) Background
(2) Proposed Change in Conditional Packaging Status Indicators Logic
4. Proposed Calculation of OPPS Scaled Payment Weights
B. Proposed Conversion Factor Update
C. Proposed Wage Index Changes
D. Proposed Statewide Average Default CCRs
E. Proposed Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B) of the Act
F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act
1. Background
2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2017
G. Proposed Hospital Outpatient Outlier Payments
1. Background
2. Proposed Outlier Calculation
H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
I. Proposed Beneficiary Copayments
1. Background
2. Proposed OPPS Copayment Policy
3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group
III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes
1. Proposed Treatment of New CY 2016 Level II HCPCS and CPT Codes Effective April 1, 2016 and July 1, 2016 for Which We Are Soliciting Public Comments in this CY 2017 OPPS/ASC Proposed Rule
2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule With Comment Period
3. Proposed Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective January 1, 2017 for Which We Are Soliciting Public Comments in This CY 2017 OPPS/ASC Proposed Rule
B. Proposed OPPS Changes—Variations Within APCs
1. Background
2. Application of the 2 Times Rule
3. Proposed APC Exceptions to the 2 Times Rule
C. Proposed New Technology APCs
1. Background
2. Proposed Additional New Technology APC Groups
3. Proposed Procedures Assigned to New Technology APC Groups for CY 2017
a. Overall Proposal
b. Retinal Prosthesis Implant Procedures
D. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
1. Imaging
2. Strapping and Cast Application (APCs 5101 and 5102)
3. Transprostatic Urethral Implant Procedure
IV. Proposed OPPS Payment for Devices
A. Proposed Pass-Through Payments for Devices
1. Expiration Dates for Current Transitional Pass-Through Devices
a. Background
b. Proposed CY 2017 Pass-Through Device Policy
2. New Device Pass-Through Applications
a. Background
b. Applications Received for Device Pass-Through Payment for CY 2017
(1) BioBag® (Larval Debridement Therapy in a Contained Dressing)
(2) ENCORE™ Suspension System
(3) Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit
3. Proposal to Change the Beginning Eligibility Date for Device Pass-Through Payment Status
4. Proposal To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Devices and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis
(a) Background
(b) Proposed CY 2017 Policy
5. Proposed Changes to Cost-to-Charge Ratios (CCRs) That Are Used To Determine Device Pass-Through Payment
a. Background
b. Proposed CY 2017 Policy
6. Proposed Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged into APC Groups
a. Background
b. Proposed CY 2017 Policy
B. Proposed Device-Intensive Procedures
1. Background
2. Proposed HCPCS Code-Level Device-Intensive Determination
3. Proposed Changes to Device Edit Policy
4. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices
a. Background
b. Proposed Policy for CY 2017
5. Proposed Payment Policy for Low Volume Device-Intensive Procedures
V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
1. Background
2. Proposal To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis
3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2016
4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2017
5. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals To Offset Costs Packaged Into APC Groups
B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status
1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals
a. Proposed Packaging Threshold
b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (Threshold Packaging Policy)
c. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes
d. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages
2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged
a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals
b. Proposed CY 2017 Payment Policy
c. Biosimilar Biological Products
3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals
4. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources
5. Proposed Payment for Blood Clotting Factors
6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data
VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
A. Background
B. Proposed Estimate of Pass-Through Spending
VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services
VIII. Proposed Payment for Partial Hospitalization Services
A. Background
B. Proposed PHP APC Update for CY 2017
1. Proposed PHP APC Changes and Effect on Geometric Mean Per Diem Costs
a. Proposed Changes to PHP APCs
b. Rationale for Proposed Changes in PHP APCs

c. Alternatives Considered
2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs and Payment Rates
a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments
b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions
3. PHP Ratesetting Process
C. Proposed Outlier Policy for CMHCs
1. Estimated Outlier Thresholds
2. Proposed CMHC Outlier Cap
3. Implementation Strategy for a Proposed 8-Percent Cap on CMHS Outlier Payments
4. Summary of Proposals
IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures
A. Background
B. Proposed Changes to the Inpatient Only (IPO) List
C. Solicitation of Public Comments on Possible Removal of Total Knee Arthroplasty (TKA) Procedures From the IPO List
1. Background
2. Discussion of TKA and the IPO List
3. Topics and Questions for Public Comment
X. Proposed Nonrecurring Policy Changes
A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider
1. Background
2. Defining Applicable Items and Services and Off-Campus Outpatient Department of a Provider As Set Forth in Sections 1833(t)(21)(A) and (B) of the Act
a. Background on the Provider-Based Status Rules
b. Proposed Exemption of Items and Services Furnished in a Dedicated Emergency Department or an On-Campus PBD as Defined at Sections 1833(t)(21)(B)(i)(I) and (II) of the Act (Excepted Off-Campus PBD)
(1) Dedicated Emergency Departments (EDs)
(2) On-Campus Locations
(3) Within the Distance From Remote Locations
c. Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act
(1) Relocation of Off-Campus PBDs Excepted Under Section 1833(t)(21)(B)(ii) of the Act
(2) Expansion of Clinical Family of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act
d. Change of Ownership and Excepted Status
e. Comment Solicitation for Data Collection Under Section 1833(t)(21)(D) of the Act
3. Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Off-Campus PBDs)
a. Background on Medicare Payment for Services Furnished in an Off-Campus PBD
b. Proposed Payment for Items and Services Furnished in Off-Campus PBD That Are Subject to Sections 1833(t)(1)(B)(v) and (t)(21)(C) of the Act
(1) Definition of "Applicable Payment System" for Nonexcepted Items and Services
(2) Definition of Applicable Items and Services and Section 603 Amendments to Section 1833(t)(1)(B) of the Act and Proposed Payment for Nonexcepted Items and Services for CY 2017
(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018
4. Beneficiary Cost-Sharing
5. Summary of Proposals
6. Proposed Changes to Regulations
B. Changes for Payment for Film X-Ray
C. Changes to Certain Scope of Services Elements for Chronic Care Management (CCM) Services
D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services
XI. Proposed CY 2017 OPPS Payment Status and Comment Indicators
A. Proposed CY 2017 OPPS Payment Status Indicator Definitions
B. Proposed CY 2017 Comment Indicator Definitions
XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
A. Background
1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System
2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services
B. Proposed Treatment of New and Revised Codes
1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes
2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2016 and July 2016 for Which We Are Soliciting Public Comments in This Proposed Rule
3. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule With Comment Period
4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period
C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services
1. Covered Surgical Procedures
a. Proposed Covered Surgical Procedures Designated as Office-Based
b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2016 and Proposed Policy for CY 2017
c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices
d. Proposed Additions to the List of ASC Covered Surgical Procedures
2. Covered Ancillary Services
D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services
1. Proposed ASC Payment for Covered Surgical Procedures
a. Background
b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2017
2. Proposed Payment for Covered Ancillary Services
a. Background
b. Proposed Payment for Covered Ancillary Services for CY 2017
E. New Technology Intraocular Lenses (NTIOLs)
1. NTIOL Application Cycle
2. Requests to Establish New NTIOL Classes for CY 2017
3. Payment Adjustment
F. Proposed ASC Payment and Comment Indicators
1. Background
2. Proposed ASC Payment and Comment Indicators
G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates
1. Background
2. Proposed Calculation of the ASC Payment Rates
a. Updating the ASC Relative Payment Weights for CY 2017 and Future Years
b. Updating the ASC Conversion Factor
3. Display of Proposed CY 2017 ASC Payment Rates
XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
A. Background
1. Overview
2. Statutory History of the Hospital OQR Program
3. Regulatory History of the Hospital OQR Program
B. Hospital OQR Program Quality Measures
1. Considerations in the Selection of Hospital OQR Program Quality Measures
2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations
3. Removal of Quality Measures from the Hospital OQR Program Measure Set
a. Considerations in Removing Quality Measures From the Hospital OQR Program
b. Criteria for Removal of "Topped-Out" Measures
4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking
5. Proposed New Hospital OQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years
a. OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure
b. OP–36: Hospital Visits after Hospital Outpatient Surgery Measure (NQF #2687)
c. OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of

Healthcare Providers and Systems (OAS CAHPS) Survey Measures
d. Summary of Previously Adopted and Newly Proposed Hospital OQR Program Measures for the CY 2020 Payment Determinations and Subsequent Years
6. Hospital OQR Program Measures and Topics for Future Consideration
a. Future Measure Topics
b. Electronic Clinical Quality Measures
c. Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing
7. Maintenance of Technical Specifications for Quality Measures
8. Public Display of Quality Measures
C. Administrative Requirements
1. QualityNet Account and Security Administrator
2. Requirements Regarding Participation Status
D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
1. Hospital OQR Program Annual Payment Determinations
2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years
3. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years and CY 2020 Payment Determination and Subsequent Years
4. Proposed Data Submission Requirements for the Proposed OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years
a. Survey Requirements
b. Vendor Requirements
5. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web Based Tool for the CY 2019 Payment Determination and Subsequent Years
6. Population and Sampling Data Requirements for the CY 2019 Payment Determination and Subsequent Years
7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years
8. Proposed Extension or Exemption Process for the CY 2019 Payment Determination and Subsequent Years
9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2019 Payment Determination and Subsequent Years—Clarification
E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2017 Payment Determination
1. Background
2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2017
XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
A. Background
1. Overview
2. Statutory History of the ASCQR Program
3. Regulatory History of the ASCQR Program
B. ASCQR Program Quality Measures
1. Considerations in the Selection of ASCQR Program Quality Measures
2. Policies for Retention and Removal of Quality Measures from the ASCQR Program
3. ASCQR Program Quality Measures Adopted in Previous Rulemaking
4. Proposed ASCQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years
a. ASC–13: Normothermia Outcome
b. ASC–14: Unplanned Anterior Vitrectomy
c. ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures
5. ASCQR Program Measure for Future Consideration
6. Maintenance of Technical Specifications for Quality Measures
7. Public Reporting of ASCQR Program Data
C. Administrative Requirements
1. Requirements Regarding QualityNet Account and Security Administrator
2. Requirements Regarding Participation Status
D. Form, Manner, and Timing of Data Submitted for the ASCQR Program
1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)
2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs
3. Requirements for Data Submitted Via a CMS Online Data Submission Tool
a. Requirements for Data Submitted via a non-CMS Online Data Submission Tool
b. Requirements for Data Submitted via a CMS Online Data Submission Tool
4. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years
5. Proposed Data Submission Requirements for the Proposed ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years
a. Survey Requirements
b. Vendor Requirements
6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years
7. ASCQR Program Reconsideration Procedures
E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements
XV. Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival
A. Background
B. Proposed Revisions to Performance Thresholds
XVI. Organ Procurement Organizations (OPOs): Changes to Definitions, Outcome Measures, and Documentation Requirements
A. Background
1. Organ Procurement Organizations (OPOs)
2. Statutory Provisions
3. HHS Initiatives Related to OPO Services
4. Requirements for OPOs
B. Proposed Provisions
1. Definition of "Eligible Death"
2. Aggregate Donor Yield for OPO Outcome Performance Measures
3. Organ Preparation and Transport-Documentation With the Organ
XVII. Transplant Enforcement Technical Corrections and Proposals
A. Technical Corrections to Transplant Enforcement Regulatory References
B. Other Proposed Revisions to § 488.61
XVIII. Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs
A. Background
B. Summary of Proposals Included in this Proposed Rule
C. Proposed Revisions to Objectives and Measures for Eligible Hospitals and CAHs
1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs
2. Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018
a. Proposed Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017
b. Proposed Changes to the Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018
D. Proposed Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs
1. Definition of "EHR Reporting Period" and "EHR Reporting Period for a Payment Adjustment Year"
2. Clinical Quality Measurement
E. Proposal to Require Modified Stage 2 for New Participants in 2017
F. Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017
G. Proposed Modifications To Measure Calculations for Actions Outside the EHR Reporting Period
XIX. Proposed Additional Hospital Value-Based Purchasing (VBP) Program Policies
A. Background
B. Proposed Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program
1. Background of the HCAHPS Survey in the Hospital VBP Program
2. Background of the Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain Performance Scoring Methodology
3. Proposed Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program Beginning With the FY 2018 Program Year
XX. Files Available to the Public Via the Internet

XXI. Collection of Information Requirements
  A. Legislative Requirements for Solicitation of Comments
  B. ICRs for the Hospital OQR Program
  C. ICRs for the ASCQR Program
  D. ICRs Relating to Proposed Changes in Transplant Enforcement Performance Thresholds
  E. ICRs for Proposed Changes to Organ Procurement Organizations (OPOs)
  F. ICRs Relating to Proposed Changes to Medicare Electronic Health Record (EHR) Incentive Program
  G. ICRs Relating to Proposed Additional Hospital VBP Program Policies
  H. ICRs for Site Neutral OPPS Payments for Off-Campus Provider-Based Departments Proposals for CY 2017
XXII. Response to Comments
XXIII. Economic Analyses
  A. Regulatory Impact Analysis
  1. Introduction
  2. Statement of Need
  3. Overall Impacts for the OPPS and ASC Payment Provisions
  4. Detailed Economic Analyses
  a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule
  (1) Limitations of Our Analysis
  (2) Estimated Effects of Proposed OPPS Changes on Hospitals
  (3) Estimated Effects of Proposed OPPS Changes on CMHCs
  (4) Estimated Effect of Proposed OPPS Changes on Beneficiaries
  (5) Estimated Effects of Proposed OPPS Changes on Other Providers
  (6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs
  (7) Alternative OPPS Policies Considered
  b. Estimated Effects of Proposed CY 2017 ASC Payment System Policies
  (1) Limitations of Our Analysis
  (2) Estimated Effects of Proposed CY 2017 ASC Payment System Policies on ASCs
  (3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries
  (4) Alternative ASC Payment Policies Considered
  c. Accounting Statements and Tables
  d. Effects of Proposed Requirements for the Hospital OQR Program
  e. Effects of Proposed Policies for the ASCQR Program
  f. Effects of Proposed Changes to Transplant Performance Thresholds
  g. Effects of Proposed Changes Relating to Organ Procurement Organizations (OPOs)
  h. Effects of Proposed Changes Relating to Medicare Electronic Health Record (EHR) Incentive Program
  i. Effects of Proposed Requirements for the Hospital VBP Program
  j. Effects of Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider
  B. Regulatory Flexibility Act (RFA) Analysis
  C. Unfunded Mandates Reform Act Analysis
  D. Conclusion
XXIV. Federalism Analysis

Regulation Text

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2017. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In addition, we are proposing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the outcome requirements for solid organ transplant programs transplant enforcement and for transplant documentation requirements; a technical correction to enforcement provisions for organ transplant centers; modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to reduce hospital administrative burden and to allow hospitals to focus more on patient care; and the removal of the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program.

Further, we are proposing policies to implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2017, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.55 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.5 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that proposed total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 would be approximately $63 billion, an increase of approximately $5.1 billion compared to estimated CY 2016 OPPS payments.

We are proposing to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.
- *Cancer Hospital Payment Adjustment:* For CY 2017, we are proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Based on those data, a proposed target PCR of 0.92 would be used to determine the CY 2017 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.92 for each cancer hospital.
- *Comprehensive APCs:* For CY 2017, we are not proposing extensive changes to the already established methodology

used for C–APCs. However, we are proposing to create 25 new C–APCs that meet the previously established criteria, which, when combined with the existing 37 C–APCs, would bring the total number to 62 C–APCs as of January 1, 2017.

- *Chronic Care Management (CCM):* For CY 2017, we are proposing some minor changes to certain CCM scope of service elements. Refer to the CY 2017 MPFS proposed rule for a detailed discussion of these changes to the scope of service elements for CCM. We are proposing that these changes will also apply to CCM furnished to hospital outpatients.
- *Device-Intensive Procedures:* For CY 2017, we are proposing that the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC be based on the median cost instead of the geometric mean cost. We believe that this approach will mitigate significant year-to-year payment rate fluctuations while preserving accurate claims-data-based payment rates for low volume device-intensive procedures. In addition, we are proposing to revise the device intensive calculation methodology and calculate the device offset amount at the HCPCS code level rather than at the APC level to ensure that device intensive status is properly assigned to all device-intensive procedures.
- *Outpatient Laboratory Tests:* For CY 2017, we are proposing to discontinue the use of the "L1" modifier to identify unrelated laboratory tests on claims. In addition, we are proposing to expand the laboratory packaging exclusion that currently applies to Molecular Pathology tests to all laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act.
- *Packaging Policies:* The OPPS currently packages many categories of items and services that are typically provided as part of the outpatient hospital service (for example, operating and recovery room, anesthesia, among others). Packaging encourages hospital efficiency, flexibility, and long-term cost containment, and it also promotes the stability of payment for services over time. In CY 2014 and 2015, we added several new categories of packaged items and services. Among these were laboratory tests, ancillary services, services described by add-on codes, and drugs used in a diagnostic test or surgical procedure. For CY 2017, we are proposing to align the packaging logic for all of the conditional packaging status indicators so that packaging would occur at the claim level (instead of based on the date of service) to promote consistency and ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies.
- *Payment Modifier for X-ray Films:* Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1833(t)(16) of the Act by adding new subparagraph (F). New section 1833(t)(16)(F)(i) of the Act provides that, effective for services furnished during 2017 or any subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS (without application of this paragraph and before application of any other adjustment) shall be reduced by 20 percent. We are proposing that, effective for services furnished on or after January 1, 2017, hospitals would be required to use a modifier on claims for X-rays that are taken using film. The use of this proposed modifier would result in a 20-percent payment reduction for the X-ray service, as specified under section 1833(t)(16)(F)(i) of the Act, of the determined OPPS payment amount (without application of paragraph (F) and before any other adjustments under section 1833(t)).
- *Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider:* We are proposing to implement section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). This provision requires that certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced as nonexcepted items and services) shall not be considered covered OPD services for purposes of OPPS payment and those items and services will instead be paid "under the applicable payment system" beginning January 1, 2017. We are making several proposals relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs may be exempt from application of payment changes under this provision.

In addition, we are proposing that the Medicare Physician Fee Schedule (MPFS) will be the "applicable payment system" for the majority of the items and services furnished by nonexcepted off-campus PBDs. We are proposing that physicians furnishing services in these departments would be paid based on the professional claim and would be paid at the nonfacility rate for services which they are permitted to bill. We are proposing to pay physicians at the nonfacility rate because we are not able to operationalize a mechanism to provide payment to the off-campus PBD for nonexcepted items and services under a payment system other than the OPPS at this time. We are clarifying that, for CY 2017, provided an off-campus PBD can meet all Federal and other requirements, a hospital also has the option of enrolling the off-campus PBD as the provider/supplier it wishes to bill as in order to meet the requirements of that payment system (such as an ASC or a group practice to be paid under the MPFS, in which case the physician would be paid at the facility rate). We intend that this payment proposal would be a transitional policy, applicable in CY 2017 only, while we continue to explore operational changes that would allow a nonexcepted off-campus PBD to bill Medicare under an applicable payment system, which, in the majority of cases, we expect will be the MPFS.

- *Ambulatory Surgical Center Payment Update:* For CY 2017, we are proposing to increase payment rates under the ASC payment system by 1.2 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.5 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2017 would be approximately $4.42 billion, an increase of approximately $214 million compared to estimated CY 2016 Medicare payments.
- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are making proposals for the CY 2018 payment determination, the CY 2019 payment determination and the CY 2020 payment determination and subsequent years. For the CY 2018 payment determination and subsequent years, we are proposing to publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that hospitals will generally have approximately 30 days to preview their data. We are also proposing to announce the timeframes for the preview period on a CMS Web site and/or on our applicable listservs. For the CY 2019

payment determination and subsequent years, we are proposing to change the timeframe for extraordinary circumstances exemptions (ECE) from 45 days to 90 days from the date that the extraordinary circumstance occurred. For the CY 2020 payment determination and subsequent years, we are proposing to adopt a total of seven measures: Two claims-based measures and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The two proposed claims-based measures are: (1) OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy and (2) OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). The five proposed survey-based measures are: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are making proposals for the CY 2018 payment determination, 2019 payment determination and CY 2020 payment determination and subsequent years. For the CY 2018 payment determination and subsequent years, we are proposing to publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that ASCs will generally have approximately 30 days to preview their data. We are also proposing to announce the timeframes for the preview period on a CMS Web site and/or on our applicable listservs. For the CY 2019 payment determination and subsequent years, we are proposing to change the submission deadline from August 15 in the year prior to the affected payment determination year to May 15 for all data submitted via a CMS Web-based tool. We also are proposing to extend the submission deadline for Extraordinary Circumstance Extensions and Exemptions requests. For the CY 2020 payment determination and subsequent years, we are proposing to adopt a total of seven measures: Two measures collected via a CMS Web-based tool and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The two proposed measures that require data to be submitted directly to CMS via a CMS Web-based tool are: (1) ASC–13: Normothermia Outcome and (2) ASC–14: Unplanned Anterior Vitrectomy. The five proposed survey-based measures are: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility.
- *Hospital Value-Based Purchasing (VBP) Program Update:* Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this proposed rule, we are proposing to remove the HCAHPS Pain Management dimension of the Hospital VBP Program, beginning with the FY 2018 program year.
- *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs:* In this proposed rule, we are proposing changes to the objectives and measures of meaningful use for Modified Stage 2 and Stage 3 starting with the EHR reporting periods in calendar year 2017. Under both Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we are proposing to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures, and lower the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. The proposal to reduce measure thresholds is intended to respond to input we have received from hospitals, hospital associations, health systems, and vendors expressing concerns about the established measures. The proposed requirements focus on reducing hospital administrative burden, allowing eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program to focus more on providing quality patient care, as well as focus on updating and optimizing CEHRT functionalities to sufficiently meet the requirements of the EHR Incentive Program and prepare for Stage 3 of meaningful use.

In addition, we are proposing changes to the EHR reporting period in calendar year 2016 for eligible professionals, eligible hospitals, and CAHs; reporting requirements for eligible professionals, eligible hospitals, and CAHs that are new participants in 2017; and the policy on measure calculations for actions outside the EHR reporting period. Finally, we are proposing a one-time significant hardship exception from the 2018 payment adjustment for certain eligible professionals who are new participants in the EHR Incentive Program in 2017 and are transitioning to the Merit-Based Incentive Payment System in 2017. We believe these proposals are responsive to additional stakeholder feedback received through both correspondence and in-person meetings and would result in continued advancement of certified EHR technology utilization, particularly among those eligible professionals, eligible hospitals and CAHs that have not previously achieved meaningful use, and result in a program more focused on supporting interoperability and data sharing for all participants under the Medicare and Medicaid EHR Incentive Programs.

- *Transplant Performance Thresholds.* With respect to solid organ transplant programs, we are proposing to restore the effective tolerance range for clinical outcomes that was allowed in our original 2007 rule. These outcomes requirements in the Medicare Conditions of Participation (CoPs) have been affected by the nationwide improvement in transplant outcomes, making it now more difficult for transplant programs to maintain compliance with, in effect, increasingly stringent Medicare standards for patient and graft survival.
- *Organ Procurement Organizations (OPOs) Changes.* In this proposed rule, we are proposing to: Change the current "eligible death" definition to be consistent with the OPTN definition; modify CMS current outcome measures to be consistent with yield calculations currently utilized by the SRTR; and modify current requirements for documentation of donor information which is sent to the transplant center along with the organ.

3. Summary of Costs and Benefits

In sections XXIII. and XXIV. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPPS Update

(1) Impacts of All OPPS Proposed Changes

Table 30 in section XXIII. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2017 compared to all estimated OPPS payments in CY 2016. We estimate that the proposed policies in this proposed rule would result in a 1.6 percent overall increase in OPPS payments to providers. We estimate that proposed total OPPS payments for CY 2017, including beneficiary cost-sharing, to the approximate 3,900 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $671 million compared to CY 2016 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate an 8.4 percent decrease in CY 2017 payments to CMHCs relative to their CY 2016 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2017 IPPS proposed rule wage indexes results in no change for urban hospitals and a 0.3 percent increase for rural hospitals under the OPPS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2017 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural and cancer hospital payment adjustments, and the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 1.6 percent to the conversion factor for CY 2017 would mitigate the impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 1.6 percent for urban hospitals and 2.3 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2017 payment rates compared to estimated CY 2016 payment rates ranges between 6 percent for musculoskeletal system procedures and −2 percent for integumentary system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2017 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2017 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

e. Impacts for Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015

We estimate that implementation of section 603 will reduce net OPPS payments by $500 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. We estimate that section 603 would increase payments to physicians under the MPFS by $170 million in CY 2017, resulting in a net Medicare Part B impact from the provision of reducing CY 2017 Part B expenditures by $330 million. These estimates include both the FFS impact of the provision and the Medicare Advantage impact of the provision. These estimates also reflect that the reduced spending from implementation of section 603 results in a lower Part B premium; the reduced Part B spending is slightly offset by lower aggregate Part B premium collections.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; and the Consolidated

Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015.

Under the OPPS, we pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include: Critical access hospitals (CAHs); hospitals located in Maryland and paid under the Maryland All-Payer Model; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, and at that time named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data, and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that: The Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add Critical Access Hospital (CAH) representation to its membership. The current charter was renewed on November 6, 2014 (80 FR 23009) and the number of panel members was revised from up to 19 to up to 15 members.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on March 14, 2016. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership, to announce new members and to announce any other changes that the public should be aware of. Beginning in CY 2017, we will transition to one meeting per year, which will be scheduled in the summer (81 FR 31941).

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments.

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: The appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the March 14, 2016 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 14, 2016 Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://facadatabase.gov/.*

F. Public Comments Received on the CY 2016 OPPS/ASC Final Rule With Comment Period

We received 25 timely pieces of correspondence on the CY 2016 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 13, 2015 (80 FR 70298), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator "NI" in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments on new or replacement Level II HCPCS codes will be set forth in the CY 2017 final rule with comment period under the appropriate subject matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For CY 2017, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2017, and before January 1, 2018 (CY 2017), using the same basic methodology that we described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70309 through 70321). That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. For this proposed rule, for the purpose of recalibrating the proposed APC relative payment weights for CY 2017, we used approximately 163 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2015, and before January 1, 2016. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this CY 2017 OPPS/ASC proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2017. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2015 and, therefore, includes codes that were in effect in CY 2015 and used for billing but were deleted for CY 2016. We are retaining these deleted bypass codes on the proposed CY 2017 bypass list because these codes existed in CY 2015 and were covered OPD services in that period, and CY 2015 claims data are used to calculate CY 2017 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more "pseudo" single procedure claims for ratesetting purposes. "Overlap bypass codes" that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2017 are identified by asterisks (*) in the fourth column of Addendum N.

We are proposing a CY 2017 bypass list of 194 HCPCS codes, as displayed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Table 1 below contains the list of codes that we are proposing to remove from the CY 2017 bypass list.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2017 BYPASS LIST

HCPCS Code	HCPCS short descriptor
95925	Somatosensory testing.
95808	Polysom any age 1–3> param.
90845	Psychoanalysis.
96151	Assess hlth/behave subseq.
31505	Diagnostic laryngoscopy.
95872	Muscle test one fiber.

b. Proposed Calculation and Use of Cost-To-Charge Ratios (CCRs)

For CY 2017, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2017 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2015 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2014. For the proposed CY 2017 OPPS payment rates, we used the set of claims processed during CY 2015. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2015 (the year of claims data we used to calculate the proposed CY 2017 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2015 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.b.(1) of this proposed rule.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2017. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html,* includes information about purchasing the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2015 claims that were used to calculate the proposed payment rates for the CY 2017 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2017, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2017 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.d. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2017 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

For details of the claims process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2017 OPPS/ASC proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Recommendations of the Advisory Panel on Hospital Outpatient Payment (the Panel) Regarding Data Development

At the March 14, 2016 meeting of the Panel, we discussed our standard analysis of APCs, specifically those APCs for which geometric mean costs in the CY 2015 claims data through September 2015 varied significantly from the CY 2014 claims data used for the CY 2016 OPPS/ASC final rule with comment period. At the March 14, 2016 Panel meeting, the Panel made three recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that CMS provide the data subcommittee a list of APCs fluctuating significantly in costs prior to each HOP Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that the work of the data subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that Michael Schroyer continue serving as subcommittee Chair for the August 2016 HOP Panel.

CMS Response: We are accepting this recommendation.

b. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2017, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also are proposing to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We are proposing to calculate the costs upon which the proposed CY 2017 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2017 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66798 through 66810), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70325 through 70339), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products will be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we are proposing to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We are inviting public comments on these proposals. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2017 payment rates for blood and blood products (which are identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(b) Solicitation of Public Comments

As discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323), we are in the process of examining the current set of HCPCS P-codes for blood products, which became effective many years ago. Because these HCPCS P-codes were created many years ago, we are considering whether this code set could benefit from some code descriptor revisions, updating, and/or consolidation to make these codes properly reflect current product descriptions and utilization while minimizing redundancy and potentially outdated descriptors. We are requesting public comments regarding the adequacy and necessity (in terms of the existing granularity) of the current descriptors for the HCPCS P-codes describing blood products. Specifically, there are three main categories of blood products: Red blood cells; platelets; and plasma. In each of these categories, there are terms that describe various treatments or preparations of the blood products, with each, in several cases, represented individually and in combination. For example, for pheresis platelets, there are codes for "leukocyte reduced," "irradiated," "leukocyte reduced + irradiated," "leukocyte reduced + irradiated + CMV-negative," among others. We are asking the blood product stakeholder community whether the current blood product HCPCS P-code descriptors with the associated granularity best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. In several cases, the hospital costs as calculated from the CMS claims data are similar for blood products of the same type (for example, pheresis platelets) that have different code descriptors, which indicates to us that there is not a significant difference in the resources needed to produce the similar products. Again, we are inviting public comments on the current set of active HCPCS P-codes that describe blood products regarding how the code descriptors could be revised and updated (if necessary) to reflect the current blood products provided to hospital outpatients. The current set of active HCPCS P-codes that describe blood products can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

In this proposed rule, for CY 2017, we are proposing to use the costs derived from CY 2015 claims data to set the proposed CY 2017 payment rates for brachytherapy sources because CY 2015 is the same year of data we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2017 OPPS. We are proposing to base the proposed payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we are proposing for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2017 and subsequent years, we also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Public Law 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

The proposed CY 2017 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator "U". We note that, for CY 2017, we are proposing to assign new proposed status indicator "E2" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2015 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPPS ratesetting methodology described earlier. Although HCPCS code C2644 became effective July 1, 2014, and although we would expect that if a hospital furnished a brachytherapy source described by this code in CY 2015, HCPCS code C2644 should appear on the CY 2015 claims, there are no CY 2015 claims reporting this code. In addition, unlike new brachytherapy sources HCPCS codes, we will not consider external data to determine a proposed payment rate for HCPCS code C2644 for CY 2017. Therefore, we are proposing to assign new proposed status indicator "E2" to HCPCS code C2644.

We are inviting public comments on this proposed policy. We also are requesting recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

c. Proposed Comprehensive APCs (C–APCs) for CY 2017

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy.

Under this policy, we designated a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator "J1," excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator "J1" are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC. In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology with the establishment of status indicator "J2". The assignment of status indicator "J2" to a specific combination of services performed in combination with each other, as opposed to a single, primary service, allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed to be not therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are outpatient department services and not therapy services. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator "J1" as a single "J1" unit procedure claim (78 FR 74871 and 79 FR 66801). We sum all line item charges for services included on the C–APC claim, convert the charges to costs, and calculate the comprehensive geometric mean cost of one unit of each service assigned to status indicator "J1." (We note that we use the term "comprehensive" to describe the geometric mean cost of a claim reporting "J1" service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, excluding claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator "J1" according to their comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator "J1" or units thereof, we identify one "J1" service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple "J1" procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported "J1" services reported on a claim map to different C–APCs, we designate the "J1" service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple "J1" services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator "J1" to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying "J1" service code combinations or code combinations of "J1" services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We implement this type of complexity adjustment when the code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule in the originating C–APC (cost threshold).

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator "J1" (or certain add-on codes) to determine if they meet the complexity adjustment criteria. For new HCPCS codes, we determine initial C–APC assignments and complexity adjustments using the best available information, crosswalking the new HCPCS codes to predecessor codes when appropriate.

Once we have determined that a particular code combination of "J1" services (or combinations of "J1" services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service-add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary "J1"service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2017, we are proposing to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator "J1" and any number of units of a single add-on code. If the frequency and cost criteria thresholds for a complexity adjustment are met, and reassignment to the next higher cost APC in the clinical family is appropriate, we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code combination to a higher cost C–APC within the same clinical family of C–APCs. If any add-on code combination reported in conjunction with the primary service code does not qualify for a complexity adjustment, payment for these services is packaged within the payment for the complete comprehensive service. We list the complexity adjustments proposed for add-on code combinations for CY 2017, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

For CY 2017, we are proposing to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described earlier) also not create a 2 times rule violation in the higher level or receiving APC (80 FR 70328). We believe that this requirement is not useful because most code combinations fall below our established frequency threshold for considering 2 times rule violations, which is described in section III.B. of this proposed rule. Therefore, because the 2 times rule would not typically apply to complexity-adjusted code combinations, we are proposing to discontinue this requirement.

We are providing in Addendum J to this proposed rule a breakdown of cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all code combinations that are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(2) Proposed C–APCs for CY 2017

(a) Proposed Additional C–APCs for CY 2017

For CY 2017 and subsequent years, we are proposing to continue to apply the C–APC payment policy methodology made effective in CY 2015, as described in detail below. We are proposing to continue to define the services assigned to C–APCs as primary services or a specific combination of services performed in combination with each other. We also are proposing to define a C–APC as a classification for the provision of a primary service or specific combination of services and all adjunctive services and supplies provided to support the delivery of the primary or specific combination of services. We also are proposing to continue to follow the C–APC payment policy methodology of packaging all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator "J1" or reporting the specific combination of services assigned to status indicator "J2," excluding services that are not covered OPD services or that cannot by statute be paid under the OPPS.

As a result of our annual review of the services and APC assignments under the OPPS, we are proposing 25 additional C–APCs to be paid under the existing C–APC payment policy beginning in CY 2017. The proposed CY 2017 C–APCs are listed in Table 2 below. All C–APCs, including those effective in CY 2016 and those being proposed for CY 2017, also are displayed in Addendum J to this proposed rule. Addendum J to this proposed rule (which is available via the Internet on the CMS Web site) also contains all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

TABLE 2—PROPOSED CY 2017 C–APCS

C–APC	CY 2017 APC title	Clinical family	Proposed new C–APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	(*)
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	(*)
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	(*)
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	(*)
5093	Level 3 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	(*)
5113	Level 3 Musculoskeletal Procedures	ORTHO	(*)
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	(*)
5154	Level 4 Airway Endoscopy	AENDO	(*)
5155	Level 5 Airway Endoscopy	AENDO	(*)
5164	Level 4 ENT Procedures	ENTXX	(*)
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5191	Level 1 Endovascular Procedures	VASCX	(*)
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5194	Level 4 Endovascular Procedures	VASCX	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	(*)
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	(*)
5302	Level 2 Upper GI Procedures	GIXXX	(*)
5303	Level 3 Upper GI Procedures	GIXXX	(*)
5313	Level 3 Lower GI Procedures	GIXXX	(*)
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	(*)
5361	Level 1 Laparoscopy & Related Services	LAPXX	
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	(*)
5374	Level 4 Urology & Related Services	UROXX	(*)
5375	Level 5 Urology & Related Services	UROXX	
5376	Level 6 Urology & Related Services	UROXX	
5377	Level 7 Urology & Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	(*)
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	(*)
5432	Level 2 Nerve Procedures	NERVE	(*)
5462	Level 2 Neurostimulator & Related Procedures	NSTIM	
5463	Level 3 Neurostimulator & Related Procedures	NSTIM	
5464	Level 4 Neurostimulator & Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	(*)
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	

TABLE 2—PROPOSED CY 2017 C–APCS—Continued

C–APC	CY 2017 APC title	Clinical family	Proposed new C–APC
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	(*)
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	(*)
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

* Proposed New C–APC for CY 2017.
C–APC CLINICAL FAMILY DESCRIPTOR KEY:
AENDO = Airway Endoscopy.
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery.
COCHL = Cochlear Implant.
EBIDX = Excision/Biopsy/Incision and Drainage.
ENTXX = ENT Procedures.
EPHYS = Cardiac Electrophysiology.
EXEYE = Extraocular Ophthalmic Surgery.
GIXXX = Gastrointestinal Procedures.
GYNXX = Gynecologic Procedures.
INEYE = Intraocular Surgery.
LAPXX = Laparoscopic Procedures.
NERVE = Nerve Procedures.
NSTIM = Neurostimulators.
ORTHO = Orthopedic Surgery.
PUMPS = Implantable Drug Delivery Systems.
RADTX = Radiation Oncology.
SCTXX = Stem Cell Transplant.
UROXX = Urologic Procedures.
VASCX = Vascular Procedures.
WPMXX = Wireless PA Pressure Monitor.

(b) Proposed New Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) C–APC

Allogeneic hematopoietic stem cell transplantation (HSCT) involves the intravenous infusion of hematopoietic stem cells derived from the bone marrow, umbilical cord blood, or peripheral blood of a donor to a recipient. Allogeneic hematopoietic stem cell collection procedures, which are performed not on the beneficiary but on a donor, cannot be paid separately under the OPPS because hospitals may bill and receive payment only for services provided to a Medicare beneficiary who is the recipient of the HSCT and whose illness is being treated with the transplant. Currently, under the OPPS, payment for these acquisition services is packaged into the APC payment for the allogeneic HSCT when the transplant occurs in the hospital outpatient setting (74 FR 60575). In the CY 2016 OPPS/ASC final rule with comment period, we assigned allogeneic HSCT to APC 5281 (Apheresis and Stem Cell Procedures), which has a CY 2016 OPPS payment rate of $3,015.

As provided in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, section 231.11, donor acquisition charges for allogeneic HSCT may include, but are not limited to, charges for the costs of several services. These services include, but are not necessarily limited to, National Marrow Donor Program fees, if applicable, tissue typing of donor and recipient, donor evaluation, physician pre-procedure donor evaluation services, costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services, among others), post-operative/post-procedure evaluation of donor, and the preparation and processing of stem cells.

When the allogeneic stem cell transplant occurs in the hospital outpatient setting, providers are instructed to report stem cell donor acquisition charges for allogeneic HSCT separately in Field 42 on Form CMS–1450 (or UB–04) by using revenue code 0819 (Organ Acquisition: Other Donor). Revenue code 0819 charges should include all services required to acquire hematopoietic stem cells from a donor, as defined earlier, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes. Revenue code 0819 maps to cost center code 086XX (Other organ acquisition where XX is "00" through "19") and is reported on line 112 (or applicable subscripts of line 112) of the Medicare cost report.

In recent years, we have received comments from stakeholders detailing concerns about the accuracy of ratesetting for allogeneic HSCT (79 FR 40950 through 40951; 79 FR 66809; and 80 FR 70414 through 70415). Stakeholders have presented several issues that could result in an inappropriate estimation of provider costs for these procedures, including outpatient allogeneic HCST reported on claims being identified as multiple procedure claims that are unusable under the standard OPPS ratesetting methodology. Stakeholders also have indicated that the requirement for the reporting of revenue code 0819 on claims reporting allogeneic HSCTs and the lack of a dedicated cost center for stem cell transplantation donor acquisition costs have led to an overly broad CCR being applied to these procedures, which comprise a very low volume of the services reported within the currently assigned cost center. In addition, commenters noted that it is likely that there are services being reported with the same revenue code (0819) and mapped to the same cost center code (086XX) as allogeneic HSCT donor acquisition charges that are unrelated to these services. Lastly, providers have commented that the donor acquisition costs of allogeneic HSCT are much higher relative to their charges when compared to the other items and services that are reported in the current cost center. Providers also have stated that hospitals have difficulty applying an appropriate markup to donor acquisition charges that will sufficiently generate a cost that approximates the total cost of donor acquisition. Through our examination of the CY 2016 claims data, we believe that the issues presented above provide a persuasive rationale for payment adjustment for donor acquisition costs for allogeneic HCST.

Stakeholders suggested that the establishment of a C–APC for stem cell transplant services would improve payment adequacy by allowing the use of multiple procedure claims, provided CMS also create a separate and distinct CCR for donor search and acquisition charges so that they are not diluted by lower cost services. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70414 through 70415), we stated that we would not create a new C–APC for stem cell transplant procedures at that time and that we would instead continue to pay for the services through the assigned APCs while continuing to monitor the issue.

Based on our current analysis of this longstanding issue and stakeholder input, for CY 2017, we are proposing to create a new C–APC 5244 (Level 4 Blood Product Exchange and Related Services) and to assign procedures described by CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) to this C–APC and to assign status indicator "J1" to the code. The creation of a new C–APC for allogeneic HSCT and the assignment of status indicator "J1" to CPT code 38240 would allow for the costs for all covered OPD services, including donor acquisition services, included on the claim to be packaged into the C–APC payment rate. These costs also will be analyzed using our comprehensive cost accounting methodology to establish future C–APC payment rates. We are proposing to establish a payment rate for proposed new C–APC 5244 of $15,267 for CY 2017.

In order to develop an accurate estimate of allogeneic HSCT donor acquisition costs for future ratesetting, for CY 2017 and subsequent years, we are proposing to update the Medicare hospital cost report (Form CMS–2552–10) by adding a new standard cost center 112.50, "Allogeneic Stem Cell Acquisition," to Worksheet A (and applicable worksheets) with the standard cost center code of "11250." The proposed new cost center, line 112.50, would be used for the recording of any acquisition costs related to allogeneic stem cell transplants as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100–04). Acquisition charges for allogeneic stem cell transplants apply only to allogeneic transplants for which stem cells are obtained from a donor (rather than from the recipient). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient) because autologous transplants involve services provided to a beneficiary only (and not to a donor), for which the hospital may bill and receive payment. Acquisition costs for allogeneic stem cells are included in the prospective payment. This cost center flows through cost finding and accumulates any appropriate overhead costs.

In conjunction with our proposed addition of the new "Allogeneic Stem Cell Acquisition" standard cost center, we are proposing to use the newly created revenue code 0815 (Allogeneic Stem Cell Acquisition Services) to identify hospital charges for stem cell acquisition for allogeneic bone marrow/stem cell transplants. Specifically, for CY 2017 and subsequent years, we are proposing to require hospitals to identify stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in Field 42 on Form CMS–1450 (or UB–04), when an allogeneic stem cell transplant occurs. Revenue code 0815 charges should include all services required to acquire stem cells from a donor, as defined above, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes. The proposed new revenue code 0815 would map to the proposed new line 112.50 (with the cost center code of "11250") on the Form CMS–2552–10 cost report. In addition, for CY 2017 and subsequent years, we are proposing to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. We are inviting public comments on these proposals.

d. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In this proposed rule, for CY 2017 and subsequent years, we are proposing to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below.

(1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We base the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In this proposed rule, for CY 2017, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2016. That is, we are proposing to use CY 2015 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2016 practice, in this proposed rule, we are proposing not to use the claims that meet these criteria in the calculation of the geometric mean costs of procedures or services assigned to APC 5375 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and APC 5641 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing to continue to calculate the proposed geometric mean costs of procedures or services assigned to APCs 5375 and 5641 using single and "pseudo" single procedure claims. We continue to believe that composite APC 8001 contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate geometric mean cost upon which to base the proposed composite APC payment rate.

Using a partial year of CY 2015 claims data available for this CY 2017 proposed rule, we were able to use 202 claims that contained both CPT codes 55875 and 77778 to calculate the proposed geometric mean cost of approximately $3,581 for these procedures upon which the proposed CY 2017 payment rate for composite APC 8001 is based.

(2) Mental Health Services Composite APC

In this proposed rule, for CY 2017, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we are proposing that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to composite APC 8010 (Mental Health Services Composite). We also are proposing to continue to set the payment rate for composite APC 8010 at the same payment rate that we are proposing to establish for APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5862 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource-intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

(3) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the "with contrast" composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the "with contrast" composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In this proposed rule, for CY 2017 and subsequent years, we are proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy will reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2017 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from a partial year of CY 2015 claims data available for this proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the final CY 2014 and CY 2015 geometric mean costs for these composite APCs, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as "overlap bypass codes" that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2017 proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

For this CY 2017 OPPS/ASC proposed rule, we were able to identify approximately 599,294 "single session" claims out of an estimated 1.6 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 38 percent of all eligible claims, to calculate the proposed CY 2017 geometric mean costs for the multiple imaging composite APCs. Table 3 below lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2017.

TABLE 3—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2017 APC 8004 (ultrasound composite)	CY 2017 Approximate APC geometric mean cost = $303
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without Contrast	
CY 2017 APC 8005 (CT and CTA without contrast composite)*	CY 2017 Approximate APC geometric mean cost = $292
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
CY 2017 APC 8006 (CT and CTA with contrast composite)	CY 2017 Approximate APC geometric mean cost = $515
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.

CY 2017 APC 8006 (CT and CTA with contrast composite)	CY 2017 Approximate APC geometric mean cost = $515
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

*If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.

Family 3—MRI and MRA with and without Contrast

CY 2017 APC 8007 (MRI and MRA without contrast composite)*	CY 2017 Approximate APC geometric mean cost = $587
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.

CY 2017 APC 8008 (MRI and MRA with contrast composite)	CY 2017 approximate APC geometric mean cost = $900
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.

CY 2017 APC 8008 (MRI and MRA with contrast composite)	CY 2017 approximate APC geometric mean cost = $900
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast,.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

*If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often results if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2017, we have examined our OPPS packaging policies, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services that are packaged into payment for the primary service that they support. In this CY 2017 proposed rule, we are proposing some modifications to our packaging policies and to package the costs of two drugs that function as supplies in a surgical procedure.

b. Proposed Clinical Diagnostic Laboratory Test Packaging Policy

(1) Background

In CY 2014, we finalized a policy to package payment for most clinical diagnostic laboratory tests in the OPPS (78 FR 74939 through 74942, and 42 CFR 419.2(b)(17)). In CY 2016, we made some minor modifications to this policy (80 FR 70348 through 70350). Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting. Specifically, we conditionally package laboratory tests and only pay separately for laboratory tests when (1) they are the only services provided to a beneficiary on a claim; (2) they are "unrelated" laboratory tests, meaning they are on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services; (3) they are molecular pathology tests; or (4) the laboratory tests are considered preventive services.

(2) Proposed "Unrelated" Laboratory Test Exception

Laboratory tests are separately paid in the HOPD when they are considered "unrelated" laboratory tests. Unrelated laboratory tests are tests on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services. Unrelated laboratory tests are designated for separate payment by hospitals with the "L1" modifier. This is the only use of the "L1" modifier.

For CY 2017, we are proposing to discontinue the unrelated laboratory test exception (and the "L1" modifier) for the following reasons: We believe that, in most cases, "unrelated" laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. Multiple hospitals have informed us that the "unrelated" laboratory test exception is not useful to them because they cannot determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim. We agree with these hospitals, and we also believe that the requirements for "unrelated" laboratory tests (different diagnosis and different ordering physician) do not necessarily correlate with the relatedness of a laboratory test to the other HOPD services that a patient receives during the same hospital stay. In the context of most hospital outpatient encounters, most laboratory tests are related in some way to other services being provided because most common laboratory tests evaluate the functioning of the human body as a physiologic system and therefore relate to other tests and interventions that a patient receives. Also, it is not uncommon for beneficiaries to have multiple diagnoses, and often times the various diagnoses are related in some way. Therefore, the associated diagnosis is not necessarily indicative of how related a laboratory test is to other hospital outpatient services performed during a hospital stay, especially give the granularity of ICD–10 diagnosis coding. Packaging of other ancillary services in the OPPS is not dependent upon a common diagnosis with the primary service into which an ancillary service is packaged. Therefore, we do not believe that this should be a requirement for laboratory test packaging. Furthermore, we believe that just because a laboratory test is ordered by a different physician than the physician who ordered the other hospital outpatient services furnished during a hospital outpatient stay does not necessarily mean that the laboratory test is not related to other services being provided to a beneficiary.

Therefore, because the "different physician, different diagnosis" criteria for "unrelated" laboratory tests do not clearly identify or distinguish laboratory tests that are integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services provided to the beneficiary during the hospital stay, we are proposing to no longer permit the use of the "L1" modifier to self-designate an exception to the laboratory test packaging under these circumstances, and seek separate payment for such laboratory tests at the CLFS payment rates. Instead, we are proposing to package any and all laboratory tests if they appear on a claim with other hospital outpatient services. We are inviting public comments on this proposal.

(3) Proposed Molecular Pathology Test Exception

In 2014, we excluded from the laboratory packaging policy molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942). In 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes. Molecular pathology laboratory tests were excluded from packaging because we believed that these relatively new tests may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged (80 FR 70348 through 70350).

In response to the CY 2016 OPPS/ASC proposed rule, commenters argued that CMS' rationale for excluding molecular pathology tests from the laboratory test packaging policy also applies to certain CPT codes that describe some new multianalyte assays with algorithmic analyses (MAAAs).

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70349 through 70350), we stated that "we may consider whether additional exceptions to the OPPS laboratory test packaging policy should apply to tests other than molecular pathology tests in the future." After further consideration, we agree with these commenters that the exception that currently applies to molecular pathology tests may be appropriately applied to other laboratory tests that, like molecular pathology tests, are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. Therefore, for

CY 2017, we are proposing an expansion of the laboratory packaging exception that currently applies to molecular pathology tests to also apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. We believe that some of these diagnostic tests that meet these criteria will not be molecular pathology tests but will also have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. We would assign status indicator "A" (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. We are inviting public comments on this proposal.

c. Conditional Packaging Status Indicators "Q1" and "Q2"

(1) Background

Packaged payment versus separate payment of items and services in the OPPS is designated at the code level through the assignment of a status indicator to all CPT and HCPCS codes. One type of packaging in the OPPS is conditional packaging, which means that, under certain circumstances, items and services are packaged, and under other circumstances, they are paid separately. There are several different conditional packaging status indicators. Two of these status indicators indicate package of the services with other services furnished on the same date of service: status indicator "Q1," which packages items or services on the same date of service with services assigned status indicator "S" (Procedure or Service, Not Discounted When Multiple), "T" (Procedure or Service, Multiple Procedure Reduction Applies), or "V" (Clinic or Emergency Department Visit); and status indicator "Q2," which packages items or services on the same date of service with services assigned status indicator "T." Other conditional packaging status indicators, "Q4" (Conditionally packaged laboratory tests) and "J1"/"J2" (Hospital Part B services paid through a comprehensive APC), package services on the same claim, regardless of the date of service.

(2) Proposed Change in Conditional Packaging Status Indicators Logic

We do not believe that some conditional packaging status indicators should package based on date of service, while other conditional packaging status indicators package based on services reported on the same claim. For CY 2017, we are proposing to align the packaging logic for all of the conditional packaging status indicators and change the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level (instead of based on the date of service) to promote consistency and ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies. We point out that this would increase the conditional packaging of conditionally packaged items and services because conditional packaging would occur whenever a conditionally packaged item or service is reported on the same claim as a primary service without regard to the date of service. We are inviting public comments on this proposal.

4. Proposed Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70350 through 70351), we applied this policy and calculated the relative payment weights for each APC for CY 2016 that were shown in Addenda A and B to that final rule with comment period (which were made available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2017, we are proposing to continue to apply the policy established in CY 2016 and calculate relative payment weights for each APC for CY 2017 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a new policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and moved the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70351). For CY 2017, we are proposing to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2017, we are proposing to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 5012 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to standardize the proposed relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2017 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2016 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2017 unscaled relative payment weights.

For CY 2016, we multiplied the CY 2016 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2015 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2017, we are proposing to apply the same process using the estimated CY 2017 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scalar by dividing the CY 2016 estimated aggregate weight by the unscaled CY 2017 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Click on the CY 2017 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

In this CY 2017 proposed rule, we are proposing to compare the estimated unscaled relative payment weights in CY 2017 to the estimated total relative payment weights in CY 2016 using CY 2015 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we are proposing to adjust the calculated CY 2017 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2017 unscaled relative payment weights by multiplying them by a weight scalar of 1.4059 to ensure that the proposed CY 2017 relative payment weights are scaled to be budget neutral. The proposed CY 2017 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the budget neutrality calculations for the CY 2017 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2016 forecast of the FY 2017 market basket increase, the proposed FY 2017 IPPS market basket update is 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2017.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), we discussed the calculation of the proposed MFP adjustment for FY 2017, which is −0.5 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this CY 2017 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2017 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2017 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2017, section 1833(t)(3)(G)(v) of the Act provides a −0.75 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act, we are proposing to apply a −0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2017.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 1.55 percent for the CY 2017 OPPS (which is 2.8 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.5 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this CY 2017 OPPS/ASC proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (8) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2016, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(v) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.75 percentage point for CY 2017.

To set the OPPS conversion factor for CY 2017, we are proposing to increase the CY 2016 conversion factor of $73.725 by 1.55 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2017 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.0000 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2017 IPPS wage indexes to those payments using the FY 2016 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For CY 2017, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2017, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2017 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2017 payments under section 1833(t) of the Act, including the proposed CY 2017 cancer hospital payment adjustment, to estimated CY 2017 total payments using the CY 2016 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2017 proposed estimated payments applying the proposed CY 2017 cancer hospital payment adjustment are identical to estimated payments applying the CY 2016 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For CY 2017, we are proposing to apply a budget neutrality adjustment factor of 1.0003 to increase the conversion factor to account for our proposal to package unrelated laboratory tests into OPPS payment.

For this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2017 would equal approximately $148.3 million, which represents 0.24 percent of total projected CY 2017 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.26 percent estimate of pass-through spending for CY 2016 and the 0.24 percent estimate of proposed pass-through spending for CY 2017, resulting in a proposed adjustment for CY 2017 of 0.02 percent. Proposed estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2017. We currently estimated that outlier payments will be 0.96 percent of total OPPS payments in CY 2016; the 1.0 percent for proposed outlier payments in CY 2017 would constitute a 0.04 percent increase in payment in CY 2017 relative to CY 2016.

For this proposed rule, we also are proposing that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we are proposing to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.45 percent (that is, the proposed OPD fee schedule increase factor of 1.55 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2017 of 73.411 for hospitals that fail to meet the Hospital OQR requirements (a difference of −1.498 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2017, we are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (8) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2017 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We are proposing to use a reduced conversion factor of 73.411 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.498 in the conversion factor relative to hospitals that met the requirements).

For CY 2017, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule.

As a result of these proposed policies, the proposed OPD fee schedule increase factor for the CY 2017 OPPS is 1.55 percent (which is 2.8 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.5 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2017, we are proposing to use a conversion factor of $74.909 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs, that is, the OPD fee schedule increase factor of 1.55 percent for CY 2017, the required wage index budget neutrality adjustment of approximately 1.0000, the cancer hospital payment adjustment of 1.0000, the packaging of unrelated laboratory tests adjustment factor of 1.0003, and the adjustment of −0.06 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2017 of $74.909.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2017 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2017 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add new paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2017 OPPS, we are proposing to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floors, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the following sections in the FY 2011 through FY 2016 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of "frontier States" as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: For FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; and for FY 2016, 80 FR 49498.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2017 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062 through 25076) for a detailed discussion of all proposed changes to the FY 2017 IPPS wage indexes. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49489 and 49494 through 49496), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), we adopted the use of the OMB labor market area delineations that were based on the 2010 Decennial Census data, effective October 1, 2014.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, "[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas." A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_default*.

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS and OPPS wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), we proposed to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to use these new definitions to calculate area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. We believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, for purposes of the OPPS, we are proposing to implement these revisions to the OMB statistical area delineations, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes. Tables 2 and 3 for the FY 2017 IPPS/LTCH PPS proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these CBSA changes. We are inviting public comments on these proposals for the CY 2017 OPPS wage indexes.

For this CY 2017 OPPS/ASC proposed rule, we are proposing to use the proposed FY 2017 hospital IPPS post-reclassified wage index for urban and rural areas as the proposed wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2017. Thus, any adjustments that were proposed for the FY 2017 IPPS post-reclassified wage index would be reflected in the proposed CY 2017 OPPS wage index, including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin No. 15–01. (We refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062 through 25076) and the proposed FY 2017 hospital wage index files posted on the CMS Web site.)

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We are proposing to continue this policy for CY 2017. The following is a brief summary of the major proposed FY 2017 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2017. We further refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062 through 25076) for a detailed discussion of the proposed changes to the FY 2017 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they would be eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2017, we are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA).

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals will maintain the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Thus, for the CY 2017 OPPS, consistent with the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25066 through 25067), this 3-year transition will continue for the third year in CY 2017.

In addition, for the FY 2017 IPPS, we proposed to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2017 (81 FR 25067 through 25068). For purposes of the CY 2017 OPPS, we also are proposing to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS so long as the IPPS continues an imputed floor policy.

For CMHCs, for CY 2017, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13–01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Consistent with our current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 2 associated with the FY 2017 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that would receive the adjustment for FY 2017. We are including the out-migration adjustment information from Table 2 associated with the FY 2017 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2017 OPPS. Addendum L is available via the Internet on the CMS Web site. With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2017 IPPS wage indexes referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2017 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2017 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For detail on our process for calculating the statewide average CCRs, we refer readers to the CY 2017 OPPS NPRM Claims Accounting Narrative that is posted on the CMS Web site. Table 4 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2017.

TABLE 4—Proposed CY 2017 Statewide Average CCRs

State	Urban/Rural	Proposed CY 2017 default CCR	Previous default CCR (CY 2016 OPPS final rule)
ALASKA	RURAL	0.472	0.588
ALASKA	URBAN	0.261	0.269
ALABAMA	RURAL	0.207	0.224
ALABAMA	URBAN	0.162	0.168
ARKANSAS	RURAL	0.215	0.223
ARKANSAS	URBAN	0.208	0.218
ARIZONA	RURAL	0.251	0.246
ARIZONA	URBAN	0.171	0.170
CALIFORNIA	RURAL	0.188	0.179
CALIFORNIA	URBAN	0.187	0.190
COLORADO	RURAL	0.356	0.366
COLORADO	URBAN	0.210	0.208
CONNECTICUT	RURAL	0.445	0.366
CONNECTICUT	URBAN	0.256	0.257
DISTRICT OF COLUMBIA	URBAN	0.293	0.298
DELAWARE	URBAN	0.303	0.308
FLORIDA	RURAL	0.170	0.170
FLORIDA	URBAN	0.145	0.150
GEORGIA	RURAL	0.242	0.251
GEORGIA	URBAN	0.192	0.199
HAWAII	RURAL	0.340	0.339
HAWAII	URBAN	0.323	0.313
IOWA	RURAL	0.295	0.305
IOWA	URBAN	0.247	0.256
IDAHO	RURAL	0.338	0.337
IDAHO	URBAN	0.452	0.459
ILLINOIS	RURAL	0.240	0.234
ILLINOIS	URBAN	0.207	0.208
INDIANA	RURAL	0.277	0.314
INDIANA	URBAN	0.233	0.237
KANSAS	RURAL	0.281	0.287
KANSAS	URBAN	0.199	0.209
KENTUCKY	RURAL	0.193	0.202
KENTUCKY	URBAN	0.190	0.203
LOUISIANA	RURAL	0.225	0.256
LOUISIANA	URBAN	0.200	0.202
MASSACHUSETTS	RURAL	0.324	0.324
MASSACHUSETTS	URBAN	0.326	0.330
MAINE	RURAL	0.452	0.470
MAINE	URBAN	0.418	0.395
MARYLAND	RURAL	0.269	0.277
MARYLAND	URBAN	0.230	0.234
MICHIGAN	RURAL	0.293	0.317
MICHIGAN	URBAN	0.319	0.319
MINNESOTA	RURAL	0.414	0.449
MINNESOTA	URBAN	0.326	0.377
MISSOURI	RURAL	0.227	0.238
MISSOURI	URBAN	0.263	0.253
MISSISSIPPI	RURAL	0.235	0.235
MISSISSIPPI	URBAN	0.168	0.169
MONTANA	RURAL	0.470	0.480
MONTANA	URBAN	0.365	0.403
NORTH CAROLINA	RURAL	0.232	0.229
NORTH CAROLINA	URBAN	0.228	0.235
NORTH DAKOTA	RURAL	0.411	0.443
NORTH DAKOTA	URBAN	0.333	0.355
NEBRASKA	RURAL	0.284	0.283
NEBRASKA	URBAN	0.239	0.238
NEW HAMPSHIRE	RURAL	0.309	0.306
NEW HAMPSHIRE	URBAN	0.279	0.306
NEW JERSEY	URBAN	0.193	0.194
NEW MEXICO	RURAL	0.240	0.280
NEW MEXICO	URBAN	0.286	0.290
NEVADA	RURAL	0.199	0.219
NEVADA	URBAN	0.129	0.146
NEW YORK	RURAL	0.303	0.311

TABLE 4—PROPOSED CY 2017 STATEWIDE AVERAGE CCRs—Continued

State	Urban/Rural	Proposed CY 2017 default CCR	Previous default CCR (CY 2016 OPPS final rule)
NEW YORK	URBAN	0.304	0.298
OHIO	RURAL	0.296	0.295
OHIO	URBAN	0.207	0.212
OKLAHOMA	RURAL	0.229	0.255
OKLAHOMA	URBAN	0.185	0.192
OREGON	RURAL	0.264	0.265
OREGON	URBAN	0.332	0.341
PENNSYLVANIA	RURAL	0.283	0.277
PENNSYLVANIA	URBAN	0.186	0.195
PUERTO RICO	URBAN	0.585	0.590
RHODE ISLAND	URBAN	0.292	0.290
SOUTH CAROLINA	RURAL	0.189	0.188
SOUTH CAROLINA	URBAN	0.194	0.197
SOUTH DAKOTA	RURAL	0.376	0.367
SOUTH DAKOTA	URBAN	0.228	0.224
TENNESSEE	RURAL	0.182	0.198
TENNESSEE	URBAN	0.179	0.177
TEXAS	RURAL	0.223	0.238
TEXAS	URBAN	0.175	0.179
UTAH	RURAL	0.368	0.493
UTAH	URBAN	0.310	0.325
VIRGINIA	RURAL	0.188	0.195
VIRGINIA	URBAN	0.231	0.233
VERMONT	RURAL	0.435	0.434
VERMONT	URBAN	0.336	0.336
WASHINGTON	RURAL	0.279	0.349
WASHINGTON	URBAN	0.301	0.308
WISCONSIN	RURAL	0.367	0.317
WISCONSIN	URBAN	0.291	0.296
WEST VIRGINIA	RURAL	0.272	0.276
WEST VIRGINIA	URBAN	0.285	0.294
WYOMING	RURAL	0.445	0.433
WYOMING	URBAN	0.320	0.311

E. Proposed Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2016. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2017 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (80 FR 39244).

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, "Transitional Adjustment to Limit Decline in Payment," to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as "held harmless").

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a "pre-BBA amount." That is, cancer hospitals are permanently held harmless to their "pre-BBA amount," and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The "pre-BBA amount" is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The "pre-BBA amount" and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are greater than other hospitals' costs, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89. For CY 2015 the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363).

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2017

For CY 2017, we are proposing to continue our policy to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. To calculate the proposed CY 2017 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2017 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2015 claims data that we used to model the impact of the proposed CY 2017 APC relative payment weights (3,716 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2017 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2015. We then removed the cost report data of the 50 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,652 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 92 percent of reasonable cost (weighted average PCR of 0.92). Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.92 for each cancer hospital. Table 5 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2017 due to the cancer hospital payment adjustment policy.

The actual amount of the CY 2017 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2017 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 5—PROPOSED ESTIMATED CY 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Proposed estimated percentage increase in OPPS payments for CY 2017
050146	City of Hope Comprehensive Cancer Center	27.2
050660	USC Norris Cancer Hospital	15.3
100079	Sylvester Comprehensive Cancer Center	33.8
100271	H. Lee Moffitt Cancer Center & Research Institute	28.7
220162	Dana-Farber Cancer Institute	51.4
330154	Memorial Sloan-Kettering Cancer Center	46.9
330354	Roswell Park Cancer Institute	31.4
360242	James Cancer Hospital & Solove Research Institute	39.4
390196	Fox Chase Cancer Center	17.9
450076	M.D. Anderson Cancer Center	54.0
500138	Seattle Cancer Care Alliance	60.4

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2016, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $3,250 (the fixed-dollar amount threshold) (80 FR 70365). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our estimate of total outlier payments as a percent of total CY 2015 OPPS payment, using CY 2015 claims available for this proposed rule and the revised OPPS expenditure estimate for the FY 2016 President's Budget, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2015, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2015 claims data and CY 2016 payment rates, we currently estimate that the aggregate outlier payments for CY 2016 will be approximately 1.0 percent of the total CY 2016 OPPS payments. We provide estimated CY 2017 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

2. Proposed Outlier Calculation

For CY 2017, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under proposed APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of this proposed rule.

To ensure that the estimated CY 2017 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $3,825.

We calculated the proposed fixed-dollar threshold of $3,825 using the standard methodology most recently used for CY 2016 (80 FR 70364 through 70365). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2016 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2017 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2015 claims using the same inflation factor of 1.0898 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270 through 25273). We used an inflation factor of 1.0440 to estimate CY 2016 charges from the CY 2015 charges reported on CY 2015 claims. The methodology for determining this charge inflation factor is discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25271). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2017 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2017 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2017, we are proposing to apply an adjustment factor of 0.9696 to the CCRs that were in the April 2016 OPSF to trend them forward from CY 2016 to CY 2017. The methodology for calculating this proposed adjustment is discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25272).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2016 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.9696 to approximate CY 2017 CCRs) to charges on CY 2015 claims that were adjusted (using the proposed charge inflation factor of 1.0898 to approximate CY 2017 charges). We simulated aggregated CY 2017 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2017 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,825, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we are proposing to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2017 OPPS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2017 scaled weight for the APC by the proposed CY 2017 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

We demonstrate below the steps on how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1," "J2," "P," "Q1," "Q2," "Q3," "Q4," "R," "S," "T," "U," or "V" (as defined in Addendum D1 to this proposed rule, which is available via the Internet on the CMS Web site), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We note that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the proposed national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the "full" national unadjusted payment rate. The proposed national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the proposed full CY 2017 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the proposed CY 2017 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The proposed wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are proposed to be assigned for FY 2017 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) "Lugar" hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. (For further discussion of the proposed changes to the FY 2017 IPPS wage indexes, as applied to the CY 2017 OPPS, we refer readers to section II.C. of this proposed rule. We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the proposed associated wage index increase developed for the FY 2017 IPPS, which are listed in Table 2 in the FY 2017 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}$.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 * (\text{national unadjusted payment rate})$.

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2017 full national unadjusted payment rate for APC 5071 is approximately $531.31. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $520.68. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for APC 5071.

The proposed FY 2017 wage index for a provider located in CBSA 35614 in New York is 1.2775. The labor-related portion of the proposed full national unadjusted payment is approximately $407.25 (.60 * $531.31 * 1.2775). The labor-related portion of the proposed reduced national unadjusted payment is approximately $399.10 (.60 * $520.68 * 1.2775). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $212.52 (.40 * $531.31). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately

$208.27 (.40 * $520.68). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $619.77 ($407.25 + $212.52). The sum of the portions of the proposed reduced national adjusted payment is approximately $607.37 ($399.10 + $208.27).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2017, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2017, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.E. of this proposed rule, for CY 2017, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in that CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which is consistent with the Congressional goal of achieving a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $106.26 is approximately 20 percent of the proposed full national unadjusted payment rate of $531.31. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/ national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2017, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2017 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicator (SI) and APC assignments. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the hospital OPPS, they are assigned to appropriate status indicators. Section XI. of this proposed rule provides a discussion of the various status indicators used under the OPPS. Certain payment status indicators provide separate payment while other payment status indicators do not.

In Table 6 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 6—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2016	Level II HCPCS Codes	April 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
July 1, 2016	Level II HCPCS Codes	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
October 1, 2016	Level II HCPCS Codes	October 1, 2016	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.

TABLE 6—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES—Continued

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
January 1, 2017	Level II HCPCS Codes	January 1, 2017	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.*	January 1, 2017	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.

* In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. We refer readers to section III.A.3. of this CY 2017 OPPS/ASC proposed rule for further discussion of this issue.

1. Proposed Treatment of New CY 2016 Level II HCPCS and CPT Codes Effective April 1, 2016 and July 1, 2016 for Which We Are Soliciting Public Comments in This CY 2017 OPPS/ASC Proposed Rule

Through the April 2016 OPPS quarterly update CR (Transmittal 3471, Change Request 9549, dated February 26, 2016), and the July 2016 OPPS quarterly update CR (Transmittal 3523, Change Request 9658, dated May 13, 2016), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2016, we made effective 10 new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2016 OPPS quarterly update CR, we allowed separate payment for 10 new Level II HCPCS codes. Table 7 below lists the 10 Level II HCPCS codes that were allowed for separate payment effective April 1, 2016.

In this CY 2017 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the Level II HCPCS codes implemented on April 1, 2016 and listed in Table 7 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 7—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2016

CY 2016 HCPCS Code	CY 2016 Long descriptor	Proposed CY 2017 status indicator	Proposed CY 2017 APC
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U	G	1844
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U	G	1846
C9461	Choline C 11, diagnostic, per study dose	G	9461
C9470	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
C9473	Injection, mepolizumab, 1 mg	G	9473
C9474	Injection, irinotecan liposome, 1 mg	G	9474
C9475	Injection, necitumumab, 1 mg	G	9475
J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	G	1845

Effective July 1, 2016, we made effective several new CPT and Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the July 2016 OPPS quarterly update CR (Transmittal 3523, Change Request 9658, dated May 13, 2016), we assigned interim OPPS status indicators and APCs for nine new Category III CPT codes and nine Level II HCPCS codes that were made effective July 1, 2016. Specifically, as displayed in Table 8 below, we made interim OPPS status indicators and APC assignments for Category III CPT codes 0438T, 0440T, 0441T, 0442T, and 0443T, and Level II HCPCS codes C9476, C9477, C9478, C9479, C9480, Q5102, Q9981, Q9982, and Q9983. We note that Category III CPT codes 0437T, 0439T, 0444T, and 0445T are assigned to OPPS status indicator "N" to indicate that the services described by the codes are packaged and their payment is included in the primary procedure codes reported with these codes.

In addition, we note that HCPCS code Q9982 replaced HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries), effective July 1, 2016. Similarly, HCPCS code Q9983 replaced HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries), effective July 1, 2016. Because HCPCS code Q9982 and Q9983 describe the same drugs as HCPCS code C9459 and C9458, respectively, we are proposing to continue their pass-through payment status, and assign the HCPCS Q-codes to the same APC and status indicators as their predecessor HCPCS C-codes, as shown in Table 8.

In addition, the CPT Editorial Panel established CPT code 0438T, effective July 1, 2016. We note that CPT code 0438T replaced HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type)), effective July 1, 2016. Because CPT code 0438T describes the same procedure as HCPCS code C9743, we are proposing to assign the CPT code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 8.

In this CY 2017 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the CPT and Level II HCPCS codes implemented on July 1, 2016. Table 8 below lists the CPT and Level II HCPCS codes that were implemented on July 1, 2016, along with the proposed status indicators and proposed APC assignments for CY 2017.

TABLE 8—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2016

CY 2016 CPT/ HCPCS Code	CY 2016 Long descriptor	Proposed CY 2017 status indicator	Proposed CY 2017 APC
C9476	Injection, daratumumab, 10 mg	G	9476
C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479	Injection, ciprofloxacin otic suspension, per vial	G	9479
C9480	Injection, trabectedin, 0.1 mg	G	9480
Q5102	Injection, Infliximab, Biosimilar, 10 mg	K	1847
Q9981	Rolapitant, oral, 1 mg	K	1761
Q9982 *	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983 **	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	G	9458
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure).	N	N/A
0438T ***	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.	T	5374
0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure).	N	N/A
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	J1	5361
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	J1	5361
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve).	J1	5361
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	T	5373
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral.	N	N/A
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral.	N	N/A

*HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) was deleted June 30, 2016, and replaced with HCPCS code Q9982 effective July 1, 2016.

**HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries) was deleted June 30, 2016, and replaced with HCPCS code Q9983 effective July 1, 2016.

***HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies) was deleted June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.

In summary, we are soliciting public comments on the proposed CY 2017 status indicators and APC assignments for the Level II HCPCS codes and the Category III CPT codes that were made effective April 1, 2016, and July 1, 2016. These codes are listed in Tables 7 and 8 of this proposed rule. We also are proposing to finalize the status indicator and APC assignments and payment rates for these codes in the CY 2017 OPPS/ASC final rule with comment period. The proposed payment rates for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS for the following calendar year.

For CY 2017, we are proposing to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to those new Level II HCPCS codes that are effective October 1 and January 1 to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the Level II HCPCS codes that will be effective October 1, 2016 and January 1, 2017 would be flagged with comment indicator "NI" in Addendum B to the CY 2017 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2017. We will be inviting public comments in the CY 2017 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes that would be finalized in the CY 2018 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective January 1, 2017, for Which We Are Soliciting Public Comments in This CY 2017 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the MPFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2017 OPPS update, we received the CY 2017 CPT codes from AMA in time for inclusion in this CY 2017 OPPS/ASC proposed rule. The new and revised CY 2017 Category I and III CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are assigned to new comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we remind readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2017 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled "CY 2017 OPPS/ASC Proposed Rule 5-Digit Placeholder Code," to this proposed rule. The final CPT code numbers will be included in the CY 2017 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator "NP."

In summary, we are soliciting public comments on the proposed CY 2017 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2017. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2017 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in § 419.2(b) of the regulations. A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2017, we are proposing that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims (or less than

1,000 claims) is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In this section of this proposed rule, for CY 2017, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

For the CY 2017 OPPS, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2017 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, we are proposing to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2017 included in this proposed rule are related to changes in costs of services that were observed in the CY 2015 claims data newly available for CY 2017 ratesetting. We also are proposing changes to the status indicators for some procedure codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2017. Addendum B to this CY 2017 OPPS/ASC proposed rule identifies with a comment indicator "CH" those procedure codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the April 1, 2016 OPPS Addendum B Update (available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing for CY 2017, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2015 claims data available for this CY 2017 proposed rule, we found 4 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we are proposing to make exceptions for under the 2 times rule for CY 2017, and identified 4 APCs that met the criteria for an exception to the 2 times rule based on the CY 2015 claims data available for this proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which has a proposed APC geometric mean cost of approximately $585. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with 2 times rule violations.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

We note that, for cases in which a recommendation by the Panel appears to result in or allow a violation of the 2 times rule, we may accept the Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 of this proposed rule lists the 4 APCs that we are proposing to make exceptions for under the 2 times rule for CY 2017 based on the criteria cited above and claims data submitted between January 1, 2015, and December 31, 2015, and processed on or before December 31, 2015. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2015, and December 31, 2015, that were processed on or before June 30, 2016, and updated CCRs, if available.

The geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

TABLE 9—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2017

Proposed CY 2017 APC	Proposed CY 2017 APC title
5521	Level 1 Diagnostic Radiology without Contrast.
5735	Level 5 Minor Procedures.
5771	Cardiac Rehabilitation.
5841	Psychotherapy.

C. Proposed New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

For CY 2016, there are 48 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1599 (New Technology—Level 48 ($90,001–$100,000)). In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of "S" (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current

New Technology APC configurations allow us to price new technology services more appropriately and consistently.

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599, vary with increments ranging from $10 to $10,000. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology Level 7 ($500–$600)) is made at approximately $550.

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures during that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe that Medicare should make full payment. However, we believe that it is most appropriate to set payment rates based on costs that are associated with providing care to Medicare beneficiaries. As claims data for new services become available, we use these data to establish payment rates for new technology APCs.

2. Proposed Additional New Technology APC Groups

As stated above, for the CY 2016 update, there are 48 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of "S" and the other set with a status indicator of "T." To improve our ability to pay appropriately for new technology services and procedures, we are proposing to expand the New Technology APC groups by adding 3 more levels, specifically, adding New Technology Levels 49 through 51. We are proposing this expansion to accommodate the assignment of retinal prosthesis implantation procedures to a New Technology APC, which is discussed in section III.C.3. of this proposed rule. Therefore, for the CY 2017 OPPS update, we are proposing to establish six new groups of New Technology APCs—APCs 1901 through 1906 (for New Technology APC Levels 49 through 51) with procedures assigned to both OPPS status indicators "S" and "T." These new groups of APCs have the same payment levels with one set subject to the multiple procedure payment reduction (procedures assigned to status indicator "T") and the other set not subject to the multiple procedure payment reduction (procedures assigned to status indicator "S"). Each proposed set of New Technology APC groups has identical group titles, payment rates, and minimum unadjusted copayments, but a different status indicator assignment. Table 10 below includes the complete list of the proposed additional six New Technology APC groups for CY 2017.

TABLE 10—PROPOSED ADDITIONAL NEW TECHNOLOGY APC GROUPS FOR CY 2017

Proposed New CY 2017 APC	Proposed CY 2017 APC group title	Proposed status indicator
1901	New Technology—Level 49 ($100,001–$120,000)	S
1902	New Technology—Level 49 ($100,001–$120,000)	T
1903	New Technology—Level 50 ($120,001–$140,000)	S
1904	New Technology—Level 50 ($120,001–140,000)	T
1905	New Technology—Level 51 ($140,001–$160,000)	S
1906	New Technology—Level 51 ($140,001–160,000)	T

The proposed payment rates for New Technology APC 1901 through 1906 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2017

a. Overall Proposal

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. However, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2017, we are proposing to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the FDA in 2013 for adult patients diagnosed with advanced retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the procedure described by HCPCS code

C1841 was assigned to OPPS status indicator "N" to indicate that payment for the procedure is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, CPT code 0100T is assigned to APC 1599 (New Technology—Level 48 ($90,001–$100,000)), which has a CY 2016 payment rate of $95,000. This payment includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believe that the CY 2016 payment rate for procedures involving the Argus® II System is insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis, which has a retail price of approximately $145,000.

For the CY 2017 update, analysis of the CY 2015 OPPS claims data used for this CY 2017 proposed rule shows 5 single claims (out of 7 total claims) for CPT code 0100T, with a geometric mean cost of approximately $141,900 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through December 31, 2015. We note that the final payment rate in the CY 2017 OPPS/ASC final rule with comment period will be based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the latest OPPS claims data available for this proposed rule and our further understanding of the Argus® II procedure, we are proposing to reassign the procedure described by CPT code 0100T from APC 1599 to APC 1906 (New Technology—Level 51 ($140,001–$160,000)), which has a proposed payment rate of approximately $150,000 for CY 2017. We believe that APC 1906 is the most appropriate APC assignment for the Argus® II procedure described by CPT code 0100T. We note that this payment rate includes the cost of both the surgical procedure, including the cost of the retinal prosthesis (noted above) (CPT code 0100T), and the cost of the Argus® II device (HCPCS code C1841). We are inviting public comments on this proposal.

D. Proposed OPPS APC-Specific Policies

1. Imaging

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we restructured the APCs that contain imaging services (80 FR 70392). The purpose of this restructuring of the OPPS APC groupings for imaging services was to improve the clinical and resource homogeneity of the services classified within the imaging APCs. Recently some stakeholders that provide imaging services in hospitals recommended some further restructuring of the OPPS imaging APCs, again for the purpose of improving the clinical and resource homogeneity of the services classified within these APCs. After reviewing the stakeholder recommendations, we agree that further improvements can be achieved by making further changes to the structure of the APC groupings of the imaging procedures classified within the imaging APCs. Therefore, for CY 2017, we are proposing to make further changes to the structure of the imaging APCs. Below in Table 11 we list the CY 2016 imaging APCs, and in Table 12 we list our proposed CY 2017 changes to the imaging APCs. This proposal would consolidate the imaging APCs from 17 APCs in CY 2016 to 8 in CY 2017. The specific APC assignments for each service grouping are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We note that some of the imaging procedures are assigned to APCs that are not listed in the tables below (for example, the vascular procedures APCs). Also, the nuclear medicine services APCs are not included in this proposal. We are inviting public comments on our proposal to consolidate the imaging APCs from 17 APCs in CY 2016 to 8 in CY 2017.

TABLE 11—CY 2016 IMAGING APCS

CY 2016 APC	CY 2016 APC Group title	CY 2016 status indicator
5521	Level 1 X-Ray and Related Services	S
5522	Level 2 X-Ray and Related Services	S
5523	Level 3 X-Ray and Related Services	S
5524	Level 4 X-Ray and Related Services	S
5525	Level 5 X-Ray and Related Services	S
5526	Level 6 X-Ray and Related Services	S
5531	Level 1 Ultrasound and Related Services	S
5532	Level 2 Ultrasound and Related Services	S
5533	Level 3 Ultrasound and Related Services	S
5534	Level 4 Ultrasound and Related Services	S
5561	Level 1 Echocardiogram with Contrast	S
5562	Level 1 Echocardiogram with Contrast	S
5570	Computed Tomography without Contrast	S
5571	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	S
5572	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography	S
5581	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	S
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	S

TABLE 12—PROPOSED CY 2017 IMAGING APCS

Proposed CY 2017 APC	Proposed CY 2017 APC group title	Proposed CY 2017 status indicator
5521	Level 1 Diagnostic Radiology without Contrast	S
5522	Level 2 Diagnostic Radiology without Contrast	S
5523	Level 3 Diagnostic Radiology without Contrast	S

TABLE 12—PROPOSED CY 2017 IMAGING APCS—Continued

Proposed CY 2017 APC	Proposed CY 2017 APC group title	Proposed CY 2017 status indicator
5524	Level 4 Diagnostic Radiology without Contrast	S
5525	Level 5 Diagnostic Radiology without Contrast	S
5571	Level 1 Diagnostic Radiology with Contrast	S
5572	Level 2 Diagnostic Radiology with Contrast	S
5573	Level 3 Diagnostic Radiology with Contrast	S

2. Strapping and Cast Application (APCs 5101 and 5102)

For the CY 2016 update, APCs 5101 (Level 1 Strapping and Cast Application) and 5102 (Level 2 Strapping and Cast Application) are assigned to OPPS status indicator "S" (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment) to indicate that the procedures and/or services assigned to these APCs are not discounted when two or more services are billed on the same date of service.

For the CY 2017 update, based on our review of the procedures assigned to APCs 5101 and 5102, we are proposing to revise the status indicator assignment for these procedures from "S" to "T" (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment) to indicate that the services are paid separately under OPPS, but a multiple procedure payment reduction applies when two or more services assigned to status indicator "T" are billed on the same date of service. Because the procedures assigned to APCs 5101 and 5102 are primarily associated with surgical treatments, we believe that the proposed reassignment of these procedures to status indicator "T" is appropriate and ensures adequate payment for the procedures, even when the multiple procedure discounting policy applies. Consequently, we also are proposing to revise the status indicator assignment for APCs 5101 and 5102 from "S" to "T" for the CY 2017 OPPS update to appropriately categorize the procedures assigned to these two APCs.

3. Transprostatic Urethral Implant Procedure

The procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is one of two procedure codes associated with the UroLift System, which is used to treat patients diagnosed with benign prostatic hyperplasia (BPH). This procedure code was assigned to New Technology APC 1564 (New Technology—Level 27 ($4500–$5000) with a payment rate of $4,750 on April 1, 2014, when the HCPCS C-code was established. We continued this APC assignment for CY 2015. For the CY 2016 update, we revised the APC assignment for the procedure described by HCPCS code C9740 from APC 1564 to APC 1565 (New Technology—Level 28 ($5000–$5500), with a payment rate of $5,250 based on the OPPS claims data used for the CY 2016 OPPS ratesetting. We further discussed the APC reassignment for the procedure described by HCPCS code C9740 in the CY 2016 OPPS/ASC final rule (80 FR 70376 through 70377).

For the CY 2017 update, review of our claims data for the procedure described by HCPCS code C9740 shows a geometric mean cost of approximately $6,312 based on 585 single claims (out of 606 total claims), which is based on claims submitted between January 1, 2015 through December 31, 2015 and processed through December 31, 2015. We note that the final CY 2017 payment rates that will be included in the CY 2017 OPPS/ASC final rule with comment period will be based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the latest OPPS claims data available for this proposed rule, we are proposing to reassign the procedure described by HCPCS code C9740 from APC 1565 to APC 5376 (Level 6 Urology and Related Services), which has a geometric mean cost of approximately $7,723. We believe that the proposed reassignment is appropriate because the geometric mean cost of approximately $6,312 for the procedure described by HCPCS code C9740 is similar to the geometric mean cost of $7,723 for APC 5376. Therefore, we are proposing to reassign the procedure described by HCPCS code C9740 from APC 1565 to APC 5376 for the CY 2017 update. The proposed CY 2017 payment rate for the procedure described by HCPCS code C9740 is included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act sets forth the period for which a device category eligible for transitional pass-through payments under the OPPS may be in effect. The implementing regulation at 42 CFR 419.66(g) provides that this pass-through payment eligibility period begins on the date CMS establishes a particular transitional pass-through category of devices. The eligibility period is for at least 2 years but no more than 3 years. We may establish a new device category for pass-through payment in any quarter. Under our current policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category; that is, the date CMS establishes a particular category of devices eligible for transitional pass-through payments. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Proposed CY 2017 Pass-Through Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are four device categories eligible for pass-through payment: (1) HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components), which was established effective January 1, 2015; (2) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), which was established effective April 1, 2015; (3) HCPCS code C2613 (Lung biopsy plug with delivery system), which was established effective July 1, 2015; and (4) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), which was established effective January 1, 2016. The pass-through payment status of the device category for HCPCS code C2624 will end on December 31, 2016. Therefore, in accordance with our current policy, we are proposing, beginning in CY 2017, to package the costs of the device described by HCPCS code C2624 into the costs related to the procedure with which the device is reported in the hospital claims data. The other three codes listed will continue with pass-through status in CY 2017.

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for temporary additional payments, referred to as "transitional pass-through payments," for devices and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for transitional pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability; (2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and (3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion. In addition, according to 42 CFR 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, which are exempt from the cost requirements as noted at §§ 419.66.(c)(3) and (e); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to us through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal, or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meets all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417).

More details on the requirements for device pass-through payment applications are included on the CMS Web site in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the "Downloads" section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application, so that the criterion of substantial clinical improvement is fully understood and can be met.

b. Applications Received for Device Pass-Through Payment for CY 2017

We received three applications by the March 1, 2016 quarterly deadline, which is the last quarterly deadline in time for this CY 2017 OPPS/ASC proposed rule. None of these three applications was approved for device pass-through payment during the quarterly review process. Applications received for the later deadlines for the remaining 2016 quarters (June 1, September 1, and December 1) will be presented in the CY 2018 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through application are included on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.* A discussion of the three applications received by the March 1, 2016 deadline is presented below.

(1) BioBag® (Larval Debridement Therapy in a Contained Dressing)

BioMonde US, LLC submitted an application for a new device pass-through category for the BioBag® (larval debridement therapy in a contained dressing) (hereinafter referred to as the BioBag®). According to the applicant, BioBag® is a biosurgical wound treatment ("maggot therapy") consisting of disinfected, living larvae (Lucilia sericata) in a polyester net bag; the larvae remove dead tissue from wounds. The BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and nonhealing traumatic or postsurgical wounds. Debridement, which is the action of removing devitalized tissue and bacteria from a wound, is required to treat or prevent infection and to allow the wound to progress through the healing process. This system contains disinfected, living larvae that remove the dead tissue from wounds and leave healthy tissue undisturbed. The larvae are provided in a sterile polyester net bag, available in different sizes. The only other similar product is free-range (that is, uncontained) larvae. Free-range larvae are not widely used in the United States because application is time consuming, there is a fear of larvae escaping from the wound, and there are concerns about proper and safe handling of the larvae. The total number of treatment cycles depends on the characteristics of the wound, the response of the wound, and the aim of the therapy. Most ulcers are completely debrided within 1 to 6 treatment cycles.

With respect to newness criterion at § 419.66(b)(1), the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 28, 2013, and its March 1, 2016 application was within 3 years of FDA clearance. The applicant claims that BioBag® is an integral part of the wound debridement, is used for one patient only, comes in contact with human skin, and is applied in or on a wound. In addition, the applicant stated that BioBag® is not an instrument, apparatus, or item for which depreciation and financing expenses are recovered. We believe that BioBag could be considered to be a surgical supply similar to a surgical dressing that facilitates either mechanical or autolytic debridement (for example, hydrogel dressings), and therefore ineligible for device pass-through payments under the provisions of § 419.66(b)(4)(ii). We are inviting public comment on whether BioBag® should be eligible under § 419.66(b) to be considered for device pass-through payment.

With respect to the existence of a previous pass-through device category that describes the BioBag®, the applicant proposed a category descriptor of "Larval therapy for the debridement of necrotic non-healing skin and soft tissue wounds." We have not identified an existing pass-through category that describes the BioBag®, but we welcome public comments on this issue.

With respect to the cost criterion, the applicant stated that BioBag® would be reported with CPT code 97602 (Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (*e.g.,* wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session). CPT code 97602 is assigned to APC 5051 (Level 1 Skin Procedures), with a CY 2016 payment rate of $117.83, and the device offset is $1.18. The price of BioBag® varies with the size of the bag ($375 to $435 per bag), and bag size selection is based on the size of the wound. To meet the cost significance criterion, there are three cost significance subtests that must be met and calculations are noted below. The first cost significance is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance, as follows for the highest-priced BioBag®: $\$435/117.83 \times 100 = 369$ percent. Thus, BioBag® meets the first cost significance test. The second cost significance test is that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list): $\$435/1.18 \times 100 = 36864$ percent. Thus, BioBag® meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: $(\$435 - 1.18)/117.83 \times 100 = 368$ percent. Thus, BioBag® meets the third cost significance test and satisfies the cost significance criterion.

With respect to the substantial clinical improvement criterion, the applicant cited a total of 18 articles relating to wound debridement, and most of these articles discussed the use of larval therapy for the treatment of ulcers. One peer-reviewed journal article described a randomized controlled trial with 267 subjects who received loose larvae, bagged larvae, or hydrogel intervention.[1] Results of the study showed that the time to healing was not significantly different between the three groups, but that larval therapy significantly reduced the time to debridement (hazard ratio for the combined larvae group compared with hydrogel was 2.31 (95 percent confidence interval 1.65 to 3.24; $P < 0.001$)); and mean ulcer related pain scores were higher in either larvae group compared with hydrogel (mean difference in pain score: loose larvae versus hydrogel 46.74 (95 percent confidence interval 32.44 to 61.04), $P < 0.001$; bagged larvae versus hydrogel 38.58 (23.46 to 53.70), $P < 0.001$).

Another article described a study of 88 patients (of which 64 patients completed the study) and patients either received a larval therapy dressing (BioFOAM) or hydrogel.[2] Because the study did not use BioBag® and there was a large drop-out rate that was not fully explained, we did not find this article helpful in determining whether the BioBag® provides a substantial clinical improvement compared to existing wound debridement modalities.

Another article that the applicant submitted was a meta-analysis of maggot debridement therapy compared to standard therapy for diabetic foot ulcers.[3] It compared four studies with a total of 356 participants and the authors concluded that maggot debridement therapy "may be a scientific and effective therapy in treatment of diabetic foot ulcers" but "the evidence is too weak to routinely recommend it for treatment."

---

[1] Dumville, et al.: Larval therapy for leg ulcers (VenUS II): randomized controlled trial).

[2] Mudge, et al.: A randomized controlled trial of larval therapy for the debridement of leg ulcers: Results of a multicenter, randomized, controlled, open, observer blind, parallel group study. *Wound Repair and Regeneration.* 2013, 1–9.

There were some additional articles provided that included a case series of maggot therapy with no control group, a retrospective study with free-range maggot therapy, maggot therapy as treatment of last resort, in vitro studies, economic modeling for wound therapy, an informational review of maggot debridement therapy and other debridement therapies, and research on other wound therapy options. These remaining articles did not assist in assessing substantial clinical improvement of BioBag® compared to existing treatments. Based on the evidence submitted with the application, we are not yet convinced that the BioBag® provides a substantial clinical improvement over other treatments for wound debridement. We are inviting public comments on whether the BioBag® meets the substantial clinical improvement criterion.

(2) Encore™ Suspension System

Siesta Medical, Inc. submitted an application for a new device pass-through category for the Encore Suspension System (hereinafter referred to as the Encore™ System). According to the application, the Encore™ System is a kit of surgical instruments and implants that are used to perform an adjustable hyoid suspension. In this procedure, the hyoid bone (the U-shaped bone in the neck that supports the tongue) and its muscle attachments to the tongue and airway are pulled forward with the aim of increasing airway size and improving airway stability in the retrolingual and hypopharyngeal airway (airway behind and below the base of tongue). This procedure is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and/or snoring, when the patient is unable to tolerate continuous positive airway pressure (CPAP). The current alternative to the hyoid suspension is the hyo-thyroid suspension technique (hyothyroidpexy). The Encore™ System is designed for hyoid bone suspension to the mandible bone using bone screws and suspension lines. The Encore™ System kit contains the following items:

- Integrated suture passer pre-loaded with polyester suture;
- Three bone screws and two bone screw inserters;
- Suspension line lock tool;
- Threading tool for suspension lines; and
- Four polyester suspension lines.

With regard to the newness criterion, the Encore™ System received FDA clearance through the section 510(k) process on March 26, 2014. Accordingly, it appears that the Encore™ System is new for purposes of evaluation for device pass-through payments.

Several components of the Encore™ System appear to be either instruments or supplies, which are not eligible for pass-through according to § 419.66(b)(4)(i) and (ii). For instance, the suture passer is an instrument and the suture is a supply, the bone screw inserters are instruments, the suspension line lock tool is an instrument, the threading tool for suspension lines is an instrument, and the polyester suspension lines are similar to sutures and therefore are supplies. With respect to the presence of a previously established code, the only implantable devices in the kit are the bone screws, and by the applicant's own admission the bone screws are described by the existing pass-through category HCPCS code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). We are inviting public comments on whether the Encore™ System bone screws are described by a previously existing category and also whether the remaining kit components are supplies or instruments.

With regard to the cost criterion, the applicant stated that the Encore™ System would be used in the procedure described by CPT code 21685 (Hyoid myotomy and suspension). CPT code 21685 is assigned to APC 5164 (Level 4 ENT Procedures) with a CY 2016 payment rate of $1616.90, and the device offset is $15.85. The price of the Encore™ System as stated in the application is $2,200. To meet the cost criterion, there are three cost significance subtests that must be met and the calculations are noted below. The first cost significance is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance: $2,200/$1,616.90 × 100 percent = 136 percent. Thus, the Encore™ System meets the first cost significance test. The second cost significance test is that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list): $2,200/$15.85 × 100 percent = 13880 percent. Thus, the Encore™ System meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: ($2,200 − $15.85)/$1,616.90 × 100 percent = 135 percent. Thus, the Encore™ System meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, the Encore™ System meets the cost criterion. However, we have concerns about whether the cost criterion would be met if based only on the kit components that are not supplies, not instruments, and not described by an existing category (if any).

With regard to the substantial clinical improvement criterion, the applicant provided a thorough review of the hyoid myotomy with suspension and other surgical procedures that treat mild or moderate obstructive sleep apnea. However, specific data addressing substantial clinical improvement with the Encore™ System was lacking.

The application included information on a case series of 17 obstructive apnea patients who received an Encore hyo-mandibular suspension as well as a previous or concurrent uvulopalatopharyngoplasty (UPPP). According to the application, the 17 patients studied demonstrated a 76 percent surgical success, and 73 percent median reduction in the Respiratory Disturbance Index (RDI) at 3 months, significantly reduced surgical time, and one infection requiring device removal. This study was a retrospective, single center study with no comparator.

In addition, the American Academy of Otolaryngology Head and Neck Surgery (AAOHNS) "Position Statement: Tongue Based Procedures" (accessed on 3.30.2016 and located at: *http://www.entnet.org/node/215*) considers the Hyoid myotomy and suspension "effective and non-investigational with proven clinical results when considered as part of the comprehensive surgical management of symptomatic adult patients with mild obstructive sleep apnea (OSA) and adult patients with moderate and severe OSA assessed as having tongue base or hypopharyngeal obstruction." The AMA CPT Editorial Panel created CPT code 21685 (Hyoid myotomy and suspension) in 2004. The AAOHNS statement and the age of the CPT code indicate that this is an established surgical procedure. The Encore™ System is a new kit of surgical instruments and implantable materials that are used to perform this procedure. According to the Encore™ System's section 510(k) Summary, "[t]he fundamental scientific technology and technological characteristics of the Encore™ System are the same as the predicate devices," which includes the Medtronic AirVance System (another surgical kit used on CPT code 21685). The applicant claimed several advantages of the Encore™ System over the AirVance System that relate to greater ease of use for the surgeon and better long-term stability. However, there are no studies comparing the Encore™ System to the AirVance System. There is no clinical data provided by the applicant to suggest that the Encore™ System kit provides a substantial clinical improvement over other instruments/implants that are used to perform Hyoid myotomy and suspension. We are inviting public comments on whether the Encore™ System meets the substantial clinical improvement criterion.

---

[3] Tian et al.: Maggot debridement therapy for the treatment of diabetic foot ulcers: a meta-analysis. *Journal of Wound Care*. Vol. 22, No. 9, 2013.

(3) Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit

Endophys Holdings, LLC. Submitted an application for a new device pass-through category for the Endophys Pressure Sensing System or Endophys Pressure Sensing Kit (hereinafter referred to as the Endophys PSS). The applicant proposed a category descriptor within either the HCPCS code C18XX series or the HCPCS code C26XX series and described by the applicant as a stand-alone catheterization sheath that is inserted percutaneously during intravascular diagnostic or interventional procedures. When applied intravascularly, the two separate functions delivering an improved patient outcome include: (1) Continuous intra-arterial blood pressure monitoring using a high-precision Fabry-Perot pressure sensor located within the device anterior approaching the distal tip of the system; and (2) a conduit that allows the introduction of other devices for cardiovascular or percutaneous interventional procedures.

The Endophys PSS is an introducer sheath (including a dilator and guidewire) with an integrated fiber optic pressure transducer for blood pressure monitoring. The Endophys PSS is used with the Endophys Blood Pressure Monitor to display blood pressure measurements. The sheath is inserted percutaneously during intravascular diagnostic or interventional procedures, typically at the site of the patient's femoral artery. This device facilitates the introduction of diagnostic and interventional devices into the coronary and peripheral vessels while continuously sensing and reporting blood pressure during the interventional procedure. Physicians would use this device to pass guidewires, catheters, stents, and coils, to perform the diagnostic or therapeutic treatment on the coronary or other vasculature. The Endophys PSS provides continuous blood pressure monitor information to the treating physician so that there is no need for an additional arterial access site for blood pressure monitoring.

With respect to the newness criterion, the Endophys PSS received FDA clearance through the section 510(k) process on January 7, 2015, and therefore is new. According to the applicant, the Endophys PSS is an integral part of various endovascular procedures, is used for one patient only, comes in contact with human skin, and is surgically implanted. Endophys PSS is not an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered, and it is not a supply or material.

With respect to the presence of a previously established category, based on our review of the application, we believe that Endophys PSS may be described by HCPCS code C1894 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser). The FDA section 510(k) Summary Product Description Section in the application describes the Endophys PSS as an introducer sheath with an integrated fiber optic pressure transducer. Because the Endophys PSS is an introducer sheath that is not guiding, not intracardiac electrophysiological, and not a laser, we believe that it is described by the previously existing category of HCPCS code C1894 established for transitional pass-through payments. We are inviting public comment on whether Endophys PSS is described by a previously existing category.

With respect to the cost criterion, according to the applicant, the Endophys PSS would be reported with CPT code 36620 (Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous). CPT code 36620 is assigned status indicator "N", which means its payment is packaged under the OPPS. The applicant stated that its device can be used in many endovascular procedures that are assigned to the APCs listed below:

APC	Description
5188	Diagnostic Cardiac Catheterization.
5191	Level 1 Endovascular Procedures.
5526	Level 6 X-Ray and Related Services.
5183	Level 3 Vascular Procedures.
5181	Level 1 Vascular Procedures.
5182	Level 2 Vascular Procedures.
5291	Thrombolysis and Other Device Revisions.

To meet the cost criterion for device pass-through payment, a device must pass all three tests for cost threshold for at least one APC. For our calculations, we used APC 5291 (Thrombolysis and Other Device Revisions), which has a CY 2016 payment rate of $199.80 and the device offset of $3.38. According to the applicant, the cost of the Endophys PSS is $2,500. The first cost significance test is that the device cost needs to be at least 25 percent of the applicable APC payment rate to reach cost significance: $\$2{,}500/199.80 \times 100$ percent = 1251 percent. Thus, the Endophys PSS meets the first cost significance test. The second cost significance test is that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list): $\$2{,}500/3.38 \times 100$ percent = 73964 percent. Thus, the Endophys PSS meets the second cost significance test. The third cost significance test is that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment: $(\$2{,}500 - 3.38)/199.80 \times 100$ percent = 1250 percent. Thus, the Endophys PSS meets the third cost significance test. Based on the costs submitted by the applicant and the above calculations, the Endophys PSS meets the cost criterion. We are inviting public comments on this issue.

With respect to the substantial clinical improvement criterion, the applicant stated that the Endophys PSS represents a substantial clinical improvement over existing medical therapies because the Endophys PSS includes a built-in pressure sensor, which eliminates the need for a second arterial line to monitor the blood pressure. The applicant stated that the Endophys PSS reduces the time to treatment for the patient (because there is no time needed to establish the second arterial line) and reduces potential complications associated with the second arterial line. While several references were provided in support of this application, there were minimal direct clinical data provided on the

Endophys PSS to support substantial clinical improvement. The application included slides with statements pertaining to cost savings, reduced morbidity and life saving for a study of 36 patients, but a published study was not submitted and additional information on study design and other details of the study were not provided. Also, the applicant provided six physician testimonials citing support for the Endophys PSS based on between one and six patient experiences with the device.

The published articles provided with the application did not provide any information based on usage of the Endophys PSS. Topics addressed in the references included: articles on intraarterial treatment for acute ischemic stroke; references providing education on blood pressure measurement and monitoring; articles on complications during percutaneous coronary intervention; and a reference on ultrasound guided placement of arterial cannulas in the critically ill. Given the paucity of studies using the Endophys PSS, we have not been persuaded that the threshold for substantial clinical improvement has been met. We are inviting public comments on whether the Endophys PSS meets the substantial clinical improvement criterion.

3. Proposal To Change the Beginning Eligibility Date for Device Pass-Through Payment Status

The regulation at 42 CFR 419.66(g) currently provides that the pass-through payment eligibility period begins on the date CMS establishes a category of devices. We are proposing to amend § 419.66(g) such that it more accurately comports with section 1833(t)(6)(B)(iii)(II)) of the Act, which provides that the pass-through eligibility period begins on the first date on which pass-through payment is made. We recognize that there may be a difference between the establishment of a pass-through category and the date of first pass-through payment for a new pass-through device for various reasons. In most cases, we would not expect this proposed change in the beginning pass-through eligibility date to make any difference in the anticipated pass-through expiration date. However, in cases of significant delay from the date of establishment of a pass-through category to the date of the first pass-through payment, by using the date that the first pass-through payment was made rather than the date on which a device category was established could result in an expiration date of device pass-through eligibility that is later than it otherwise would have been had the clock began on the date the category was first established. We are inviting public comments on our proposal.

4. Proposal To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Devices and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

a. Background

As required by statute, transitional pass-through payments for a device described in section 1833(t)(6)(B)(iii) of the Act can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the product. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for new pass-through devices on a quarterly basis through the next available OPPS quarterly update after the approval of a device's pass-through status. However, we expire pass-through status for devices on a calendar-year basis through notice-and-comment rulemaking rather than on a quarterly basis. Device pass-through status currently expires at the end of a calendar year when at least 2 years of pass-through payments have been made, regardless of the quarter in which it was initially approved. This means that the duration of the pass-through eligibility for a particular device will depend upon when during a year the applicant applies and is approved for pass-through payment. For example, a new pass-through device with pass-through status effective on April 1 would receive 2 years and 3 quarters of pass-through status while a pass-through device with pass-through status effective on October 1 would receive 2 years and 1 quarter of pass-through status.

b. Proposed CY 2017 Policy

We are proposing, beginning with pass-through devices newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through status for devices to afford a pass-through period that is as close to a full 3 years as possible for all pass-through payment devices. This proposed change would eliminate the variability of the pass-through eligibility period, which currently varies based on the timing of the particular application. For example, under this proposal, for a device with pass-through first effective on October 1, 2017, pass-through status would expire on September 30, 2020. We believe that the payment adjustment for transitional pass-through payments for devices under the OPPS is intended to provide adequate payment for new innovative technology while we collect the necessary data to incorporate the costs for these devices into the calculation of the associated procedure payment rate (66 FR 55861). We believe that the 3-year maximum pass-through period for all pass-through devices will better insure robust data collection and more representative procedure payments once the pass-through devices are packaged. We are inviting public comments on this proposal.

5. Proposed Changes to Cost-to-Charge Ratios (CCRs) That Are Used To Determine Device Pass-Through Payments

a. Background

Section 1833(t)(6)(D)(ii) of the Act and 42 CFR 419.66(h) describe how payment will be determined for device pass-through devices. Currently, transitional pass-through payments for devices are calculated by taking the hospital charges for each billed device, reducing them to cost by use of the hospital's average CCR across all outpatient departments, and subtracting an amount representing the device cost contained in the APC payments for procedures involving that device (65 FR 18481 and 65 FR 67809). In the original CY 2000 OPPS final rule, we stated that we would examine claims in order to determine if a revenue center-specific set of CCRs should be used instead of the average CCR across all outpatient departments (65 FR 18481).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), CMS created a cost center for "Medical Supplies Charged to Patients," which are generally low cost supplies, and another cost center for "Implantable Devices Charged to Patients," which are generally high-cost implantable devices. This change was in response to a Research Triangle Institute, International (RTI) study that was discussed in the FY 2009 IPPS final rule and which determined that there was charge compression in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies. Charge compression can result in undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR (such as the hospital wide CCR) is applied to items of widely varying costs in the same cost center. By splitting medical supplies and implantable devices into two cost centers, some of the effects of charge compression were mitigated. The cost center for "Implantable Devices Charged to Patients" has been available for use for OPPS cost reporting periods beginning on or after May 1, 2009.

In CY 2013, we began using data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for use in calculating the OPPS relative payment weights for CY 2013 (77 FR 68225). Hospitals have adapted their cost reporting and coding practices in order to report usage to the "Implantable Devices Charged to Patients" cost center, resulting in sufficient data to perform a meaningful analysis. However, we have continued to use the hospital-wide CCR in our calculation of device pass-through payments. We have received a request to consider using the "Implantable Devices Charged to Patients" CCR in the calculation of device pass-through payment and have evaluated this request. An analysis of the CCR data for this proposed rule indicates that about two-thirds of providers have an "Implantable Devices Charged to Patients" CCR. For the hospitals that have an "Implantable Devices Charged to Patients" CCR, the median is 0.3911, compared with a median hospital-wide CCR of 0.2035.

b. Proposed CY 2017 Policy

We are proposing to use the more specific "Implantable Devices Charged to Patients" CCR instead of the less specific average hospital-wide CCR to calculate transitional pass-through payments for devices, beginning with device pass-through payments in CY 2017. When the CCR for the "Implantable Devices Charged to Patients" CCR is not available for a particular hospital, we would continue to use the average CCR across all outpatient departments to calculate pass-through payments. We believe using the "Implantable Devices Charged to Patients" CCR will provide more accurate pass-through payments for most device pass-through payment recipients and will further mitigate the effects of charge compression. We are inviting public comments on this proposal.

6. Proposed Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device), exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the pass-through payment amount for the eligible device. We have an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). In the unusual case where the device offset amount exceeds the device pass-through payment amount, the regular APC rate would be paid and the pass-through payment would be $0.

b. Proposed CY 2017 Policy

For CY 2017, we are proposing to calculate the portion of the otherwise applicable Medicare OPD fee schedule amount, for each device-intensive procedure payment rate that can reasonably be attributed to (that is, reflect) the cost of an associated device (the device offset amount) at the HCPCS code level rather than at the APC level (which is an average of all codes assigned to an APC). We refer readers to section IV.B. of this proposed rule for a discussion of this proposal. Otherwise, we will continue our established practice of reviewing each new pass-through device category to determine whether device costs associated with the new category replace device costs that are already packaged into the device implantation procedure. If device costs that are packaged into the procedure are related to the new category, then according to our established practice we will deduct the device offset amount from the pass-through payment for the device category. The list of device offsets for all device procedures will be posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, device-intensive APCs are defined as those APCs with a device offset greater than 40 percent (79 FR 66795). In assigning device-intensive status to an APC, the device costs of all of the procedures within the APC are calculated and the geometric mean device offset of all of the procedures must exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilize devices, and the device costs for the associated HCPCS codes exceed the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this proposed rule. A related device policy is the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

2. Proposed HCPCS Code-Level Device-Intensive Determination

As stated above, currently the device-intensive methodology assigns device-intensive status to all procedures requiring the implantation of a device, which are assigned to an APC with a device offset greater than 40 percent. Historically, the device-intensive designation has been at the APC level and applied to the applicable procedures within that given APC. For CY 2017, we are proposing to modify the methodology for assigning device-intensive status. Specifically, for CY 2017, we are proposing to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment, as we no longer believe that device-intensive status should be based on APC assignment because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. In 2016, we restructured many of the APCs, and this resulted in some procedures with significant device costs not being assigned device-intensive status because they were not assigned to a device-intensive APC. Under our proposal, all procedures with significant device costs (defined as a device offset of more than 40 percent) would be assigned device-intensive status, regardless of their APC placement. Also, we believe that a HCPCS code-level device offset would, in most cases, be a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that such a methodological change would result in a more accurate representation of the cost attributable to implantation of a high-cost device, which would ensure consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset would remove inappropriate device-intensive status to procedures without a significant device cost but which are granted such status because of APC assignment.

Under our proposal, procedures that have an individual HCPCS code-level device offset of greater than 40 percent would be identified as device-intensive procedures and would be subject to all the CY 2016 policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and device credits. Therefore, under our proposal, all procedures requiring the implantation of a medical device and that have an individual HCPCS code-level device offset of greater than 40 percent would be subject to the device edit and no cost/full credit and partial credit device policies, discussed in sections IV.B.3. and IV.B.4. of this proposed rule, respectively. We are proposing to amend the regulation at § 419.44(b)(2) to reflect that we would no longer be designating APCs as device-intensive, and instead would be designating procedures as device-intensive.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, we are proposing to apply device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent would not be calculated from claims data; instead it would be applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41 percent default device offset to new codes that describe procedures that implant medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer. Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status would be applied to the code if the HCPCS code-level device offset is greater than 40 percent, according to our proposed policy of determining device-intensive status by calculating the HCPCS code-level device offset. The full listing of proposed device-intensive procedures is included in a new Addendum P to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Changes to the Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

As part of our proposal described in section IV.B.2. of this proposed rule to no longer recognize device-intensive APCs and instead recognize device-intensive procedures based on their individual HCPCS code-level device offset being greater than 40 percent, for CY 2017, we are proposing to modify our existing device edit policy. Specifically, for CY 2017 and subsequent years, we are proposing to apply the CY 2016 device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures. In addition, we are proposing that any device code, when reported on a claim with a device-intensive procedure, would satisfy the edit.

4. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the "FB" modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the "FC" modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" and "FC" modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the "FD" value code appears on a claim. For CY 2015, we continued our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Proposed Policy for CY 2017

For CY 2017, we are proposing modifications to our current policy for reducing OPPS payment by the full or partial credit a provider receives for a replaced device, in conjunction with our proposal above to recognize the newly defined (individual HCPCS level device offset greater than 40 percent) device-intensive procedures. For CY 2017 and subsequent years, we are proposing to reduce OPPS payment for specified procedures when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, for CY 2017, we are proposing to continue to reduce the OPPS payment, for the device-intensive procedures, by the full or partial credit a provider receives for a replaced device. Under this proposed policy, hospitals would continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

For CY 2017 and subsequent years, we also are proposing to determine which procedures our proposed policy would apply to using three criteria analogous to the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our existing policy applies (71 FR 68072 through 68077). Specifically, for CY 2017 and subsequent years, we are proposing to use the following three criteria for determining the procedures to which our proposed policy would apply: (1) All procedures must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the procedure must be device-intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost. We continue to believe these criteria are appropriate because no-cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the procedure into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost. As noted earlier in this section, procedures with a device offset that exceed the 40-percent threshold are called device-intensive procedures.

5. Proposed Payment Policy for Low-Volume Device-Intensive Procedures

For CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We note that we are proposing to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs), and we believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we are proposing a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In particular, we are proposing that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described above for the policy applied to the procedure described by CPT code 0308T in CY 2016. We believe that this approach will help to mitigate to some extent significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures. For CY 2017, this policy would only apply to a procedure described by CPT code 0308T in APC 5495 because this APC is the only APC containing a device-intensive procedure with less than 100 total claims in the APC. The CY 2017 proposed rule geometric mean cost for the procedure described by CPT code 0308T (based on 30 claims) is approximately $7,762, and the median cost is approximately $15,567. The proposed CY 2017 payment rate (calculated using the median cost) is approximately $17,188.90. We are inviting public comments on this proposal.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. Throughout this proposed rule, the term "biological" is used because this is the term that appears in section 1861(t) of the Act. "Biological" as used in this proposed rule includes (but is not necessarily limited to) "biological product" or "biologic" as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to drugs or biologicals that are outpatient hospital services under Medicare Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2017 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. Proposal To Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for new pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, we expire pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). This means that because the 2-year to 3-year pass-through payment eligibility period starts on the date of first pass-through payment under 42 CFR 419.64(c)(2), the duration of pass-through eligibility for a particular drug or biological will depend upon when during a year the applicant applies for pass-through status. Under the current policy, a new pass-through drug or biological with pass-through status effective on January 1 would receive 3 years of pass-through status; a pass-through drug with pass-through status effective on April 1 would receive 2 years and 3 quarters of pass-through status; a pass-through drug with pass-through status effective on July 1 would receive 2 and 1/2 years of pass-through status; and a pass-through drug with pass-through status effective on October 1 would receive 2 years and 3 months (a quarter) of pass-through status.

We are proposing, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs and biologicals to afford a pass-through period that is as close to a full 3 years as possible for all pass-through payment drugs, biologicals, and radiopharmaceuticals. This proposed change would eliminate the variability of the pass-through payment eligibility period, which currently varies based on the timing of the particular application, as we now believe that the timing of a pass-through payment application should not determine the duration of pass-through payment status. For example, for a drug with pass-through status first effective on April 1, 2017, pass-through status would expire on March 31, 2020. This approach would allow for the maximum pass-through period for each pass-through drug without exceeding the statutory limit of 3 years. We are inviting public comments on this proposal.

3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2016

We are proposing that the pass-through status of 15 drugs and biologicals would expire on December 31, 2016, as listed in Table 13 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals were approved for pass-through status on or before January 1, 2015. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $110 for CY 2017), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we are proposing to package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we are proposing to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2017, as discussed further in section V.B.3. of this proposed rule).

TABLE 13—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2016

CY 2016 HCPCS Code	CY 2016 Long descriptor	CY 2016 Status indicator	CY 2016 APC
C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1322	Injection, elosulfase alfa, 1mg	G	1480
J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1447	Injection, TBO-Filgrastim, 1 microgram	G	1748
J3145	Injection, testosterone undecanoate, 1 mg	G	1487
J3380	Injection, vedolizumab, 1 mg	G	1489
J7181	Injection, factor xiii a-subunit, (recombinant), per iu	G	1746
J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	G	1486
J7205	Injection, factor viii fc fusion (recombinant), per iu	G	1656
J7508	Tacrolimus, extended release, (astagraf xl), oral, 0.1 mg	G	1465
J9301	Injection, obinutuzumab, 10 mg	G	1476
J9308	Injection, ramucirumab, 5 mg	G	1488
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
Q4121	Theraskin, per square centimeter	G	1479

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2017

We are proposing to continue pass-through payment status in CY 2017 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016. These drugs and biologicals, which were approved for pass-through status between January 1, 2014, and July 1, 2016, are listed in Table 14 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2016 are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2017, we are proposing to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2017. We are proposing that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2017 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2017 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2017 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

In CY 2017, as is consistent with our CY 2016 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2017, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The 38 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2017 or have been granted pass-through payment status as of July 2016 are shown in Table 14 below.

TABLE 14—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2017

CY 2016 HCPCS Code	CY 2017 HCPCS Code	CY 2017 Long descriptor	Proposed CY 2017 status indicator	Proposed CY 2017 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9137	C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U..	G	1844
C9138	C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	G	1846
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9460	C9460	Injection, cangrelor, 1 mg	G	9460
C9461	C9461	Choline C 11, diagnostic, per study dose	G	9461
C9470	C9470	Injection, aripiprazole lauroxil, 1 mg	G	9470
C9471	C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
C9472	C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU).	G	9472
C9473	C9473	Injection, mepolizumab, 1 mg	G	9473
C9474	C9474	Injection, irinotecan liposome, 1 mg	G	9474
C9475	C9475	Injection, necitumumab, 1 mg	G	9475
C9476	C9476	Injection, daratumumab, 10 mg	G	9476
C9477	C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479	C9479	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	C9480	Injection, trabectedin, 0.1 mg	G	9480
J0596	J0596	Injection, c1 esterase inhibitor (recombinant), Ruconest, 10 units	G	9445
J0695	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
J0875	J0875	Injection, dalbavancin, 5 mg	G	1823
J1833	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
J2407	J2407	Injection, oritavancin, 10 mg	G	1660
J2502	J2502	Injection, pasireotide long acting, 1 mg	G	9454
J2547	J2547	Injection, peramivir, 1 mg	G	9451
J2860	J2860	Injection, siltuximab, 10 mg	G	9455
J3090	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
J7313	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
J8655	J8655	Netupitant 300 mg and palonosetron 0.5 mg	G	9448
J9032	J9032	Injection, belinostat, 10 mg	G	1658
J9039	J9039	Injection, blinatumomab, 1 microgram	G	9449
J9271	J9271	Injection, pembrolizumab, 1 mg	G	1490
J9299	J9299	Injection, nivolumab, 1 mg	G	9453
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

5. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged Into APC Groups

Under 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2017, as we did in CY 2016, we are proposing to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a diagnostic radiopharmaceutical payment offset may be applicable are the same as for CY 2016 (80 FR 70430). Also, the proposed APCs to which a contrast agent payment offset may be applicable, a stress agent payment offset, or a skin substitute payment offset are also the same as for CY 2016 (80 FR 70431 through 70432).

We are proposing to continue to post annually on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $100 for CY 2016 (80 FR 70433).

Following the CY 2007 methodology, for this CY 2017 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2017 and rounded the resulting dollar amount ($109.03) to the nearest $5 increment, which yielded a figure of $110. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). We refer below to this series generally as the PPI for Prescription Drugs. Based on these calculations, we are proposing a packaging threshold for CY 2017 of $110.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs")

To determine the proposed CY 2017 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called "threshold-packaged" drugs) that had a HCPCS code in CY 2015 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2015 claims processed before January 1, 2016 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2017: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2017, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2017, as discussed in more detail in section V.B.2.b. of this proposed rule) to calculate the CY 2017 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2015 (data that were used for payment purposes in the physician's office setting, effective April 1, 2016) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2017, we are proposing to use payment rates based on the ASP data from the first quarter of CY 2016 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2016. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2015 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $110, and identify items with a per day cost greater than $110 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2015 HCPCS codes that were reported to the CY 2016 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2017.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2017 OPPS/ASC proposed rule, we are proposing to use ASP data from the first quarter of CY 2016, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2016, along with updated hospital claims data from CY 2015. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2017 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule will be based on ASP data from the second quarter of CY 2016. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2016. These payment rates would then be updated in the January 2017 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2017. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2015 claims data and updated cost report information available for the CY 2017 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2017 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2017 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2017 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2016. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434).

c. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). We continued the high cost/low cost categories policy in CY 2015 and CY 2016, and are proposing to continue it for CY 2017. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For CY 2017, as in CY 2016, we are proposing to determine the high/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. For a discussion of the CY 2016 high cost/low cost methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). We are proposing to assign skin substitutes that exceed either the MUC or PDC threshold to the high cost group. We are proposing to assign skin substitutes with an MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2017, we analyzed CY 2015 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2017 MUC threshold is \$25 per cm^2 (rounded to the nearest \$1) and the proposed CY 2017 PDC threshold is \$729 (rounded to the nearest \$1).

For CY 2017, as in CY 2016, we are proposing to continue to assign skin substitutes with pass-through payment status to the high cost category, and to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2017 MUC threshold. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). In addition, as in CY 2016, we are proposing for CY 2017 that a skin substitute that is both assigned to the high cost group in CY 2016 and also exceeds either the MUC or PDC in this proposed rule for CY 2017 would be assigned to the high cost group for CY 2017, even if it no longer exceeds the MUC or PDC CY 2017 thresholds based on updated claims data and pricing information used in the CY 2017 final rule with comment period. Table 15 below displays the proposed CY 2017 high cost or low cost category assignment for each skin substitute product.

TABLE 15—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2017

CY 2017 HCPCS Code	CY 2017 Short descriptor	Proposed CY 2017 high/low assignment
C9349*	PuraPly, PuraPly antimic	High.
C9363	Integra Meshed Bil Wound Mat	High.
Q4100	Skin Substitute, NOS	Low.
Q4101	Apligraf	High.
Q4102	Oasis Wound Matrix	Low.

TABLE 15—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2017—Continued

CY 2017 HCPCS Code	CY 2017 Short descriptor	Proposed CY 2017 high/low assignment
Q4103	Oasis Burn Matrix	High.
Q4104	Integra BMWD	High.
Q4105	Integra DRT	High.
Q4106	Dermagraft	High.
Q4107	GraftJacket	High.
Q4108	Integra Matrix	High.
Q4110	Primatrix	High.
Q4111	Gammagraft	Low.
Q4115	Alloskin	Low.
Q4116	Alloderm	High.
Q4117	Hyalomatrix	Low.
Q4119	Matristem Wound Matrix	Low.
Q4120	Matristem Burn Matrix	High.
Q4121	Theraskin	High.
Q4122	Dermacell	High.
Q4123	Alloskin	High.
Q4124	Oasis Tri-layer Wound Matrix	Low.
Q4126	Memoderm/derma/tranz/integup	High.
Q4127	Talymed	High.
Q4128	Flexhd/Allopatchhd/Matrixhd	High.
Q4129	Unite Biomatrix	High.
Q4131	Epifix	High.
Q4132	Grafix Core	High.
Q4133	Grafix Prime	High.
Q4134	hMatrix	Low.
Q4135	Mediskin	Low.
Q4136	Ezderm	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	High.
Q4138	Biodfence DryFlex, 1cm	High.
Q4140	Biodfence 1cm	High.
Q4141	Alloskin ac, 1cm	High.
Q4143	Repriza, 1cm	High.
Q4146	Tensix, 1cm	High.
Q4147	Architect ecm, 1cm	High.
Q4148	Neox 1k, 1cm	High.
Q4150	Allowrap DS or Dry 1 sq cm	High.
Q4151	AmnioBand, Guardian 1 sq cm	High.
Q4152	Dermapure 1 square cm	High.
Q4153	Dermavest 1 square cm	High.
Q4154	Biovance 1 square cm	High.
Q4156	Neox 100 1 square cm	High.
Q4157	Revitalon 1 square cm	High.
Q4158	MariGen 1 square cm	High.
Q4159	Affinity 1 square cm	High.
Q4160	NuShield 1 square cm	High.
Q4161	Bio-Connekt per square cm	Low.
Q4162	Amnio bio and woundex flow	Low.
Q4163	Amnion bio and woundex sq cm	Low.
Q4164	Helicoll, per square cm	High.
Q4165	Keramatrix, per square cm	Low.

* Pass-through payment status in CY 2017.

d. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2017.

For CY 2017, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2015 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2017 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2015 claims data to make the proposed packaging determinations for these drugs: HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg), J1850 (Injection, kanamycin sulfate, up to 75 mg) and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2017 drug packaging threshold of $110 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2017 drug packaging threshold of $110 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2017 is displayed in Table 16 below.

TABLE 16—PROPOSED HCPCS CODES TO WHICH THE CY 2017 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2017 HCPCS Code	CY 2017 Long descriptor	Proposed CY 2017 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular, over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution, 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml = 1 unit)	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary.

We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2017 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CY 2014, CY 2015, and CY 2016 (80 FR 70440).

b. Proposed CY 2017 Payment Policy

For CY 2017 and subsequent years, we are proposing to continue our payment policy that has been in effect from CY 2013 to present and pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS Web site), which illustrate the proposed CY 2017 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2016, or WAC, AWP, or mean unit cost from CY 2015 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2017 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2017 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2016 (July 1, 2016 through September 30, 2016) will be used to set the payment rates that are released for the quarter beginning in January 2017 near the end of December 2016. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 2016 are based on mean unit cost in the available CY 2015 claims data. If ASP information becomes available for payment for the quarter beginning in January 2017, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this proposed rule (reflecting April 2016 ASP data) that do not have ASP information available for the quarter beginning in January 2017. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2015 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2017 payment purposes and are only illustrative of the proposed CY 2017 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

c. Biosimilar Biological Products

For CY 2016, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (80 FR 70445 through 70446). For CY 2017, we are proposing to continue this same payment policy for biosimilar biological products.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2017, we are proposing to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2017. Therefore, we are proposing for CY 2017 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2015 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2017 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

4. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). We have reassessed this payment for CY 2017 and did not identify any new information that would cause us to modify payment. Therefore, for CY 2017, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

5. Proposed Payment for Blood Clotting Factors

For CY 2016, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (80 FR 70441). That is, for CY 2016, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2016 updated furnishing fee was $0.202 per unit.

For CY 2017, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

For CY 2017, we are proposing to continue to use the same payment policy as in CY 2016 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data (80 FR 70443). The proposed CY 2017 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2017 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2017. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2016 or beginning in CY 2017. The sum of the CY 2017 pass-through spending estimates for these two groups of device categories equals the total CY 2017 pass-through spending estimate for device categories with pass-through payment status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in this proposed rule for CY 2017, we are proposing to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2017, we also are proposing to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2017 OPPS at ASP+6 percent, and because we are proposing to pay for CY 2017 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2017 for this group of items is $0, as discussed below.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule. We are proposing that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2017. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2017 is not $0, as discussed below. In section V.A.4. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2017. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible in the remaining quarters of CY 2016 or beginning in CY 2017. The sum of the CY 2017 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2017 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2017, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2016 (80 FR 70446 through 70448).

For the first group, consisting of device categories that are currently eligible for pass–through payment and will continue to be eligible for pass-through payment in CY 2017, there are three active categories for CY 2017. For CY 2016, we established one new device category subsequent to the publication of the CY 2016 OPPS/ASC proposed rule, HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), that was effective January 1, 2016. We estimate that the device described by HCPCS code C1822 will cost $1 million in pass-through expenditures in CY 2017. Effective April 1, 2015, we established that the device described by HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) will be eligible for pass-through payment. We estimate that the device described by HCPCS code C2623 will cost $97 million in pass-through expenditures in CY 2017. Effective July 1, 2015, we established that the device described by HCPCS code C2613 (Lung biopsy plug with delivery system) will be eligible for pass-through payment. We estimate that the device described by HCPCS code

C2613 will cost $4.7 million in pass-through expenditures in CY 2017. Based on the three device categories of HCPCS codes C1822, C2623, and C2613, we are proposing an estimate for the first group of devices of $102.7 million.

In estimating our proposed CY 2017 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2017; additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2017; and contingent projections for new device categories established in the second through fourth quarters of CY 2017. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2017 pass-through spending for this second group of device categories is $10 million.

To estimate proposed CY 2017 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for CY 2017, we proposed to use the most recent Medicare physician claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2017 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2017, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we are proposing to include in the CY 2017 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For this proposed rule, using the proposed methodology described above, we calculated a CY 2017 proposed spending estimate for this first group of drugs and biologicals of approximately $19.0 million.

To estimate proposed CY 2017 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2017, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2016, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2017), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2017 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2017 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $16.6 million.

In summary, in accordance with the methodology described earlier in this section, for this proposed rule, we estimate that proposed total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2017 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2017 would be approximately $148.3 million (approximately $112.7 million for device categories and approximately $35.6 million for drugs and biologicals), which represents 0.24 percent of total projected OPPS payments for CY 2017. Therefore, we estimate that proposed pass-through spending in CY 2017 would not amount to 2.0 percent of total projected OPPS CY 2017 program spending.

VIII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2017, we are proposing to continue with and are not proposing any changes to our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also are proposing to continue with and are not proposing any change to our payment policy for critical care services for CY 2017. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). We are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We encourage those parties who comment to provide the data and analysis necessary to justify any proposed changes.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act requires the Secretary to establish relative payment weights for covered OPD services (and any groups of such services described in section 1833(t)(2)(B) of the Act) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

We began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697). For CY 2010, we retained the two-tiered payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and 0176 (for Level 2 services)), based on each provider type's own unique data. In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990). For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC PHP APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. We established these four

PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we again continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type. We also implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than 5 (CCR > 5) to calculate costs for at least one of their component services, and a trim on CMHCs with an average cost per day that is above or below 2 (±2) standard deviations from the mean. We also renumbered the PHP APCs which were previously 0172, 0173, 0175, and 0176, to 5851, 5852, 5861, and 5862, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467).

In the effort to increase the accuracy of the PHP per diem costs, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70461), we completed an extensive analysis of the claims and cost data, which included provider service usage, coding practices, and the ratesetting methodology. This extensive analysis identified provider coding errors that were inappropriately removing costs from ratesetting, and aberrant data from several providers that were affecting the calculation of the proposed PHP geometric mean per diem costs. Aberrant data are claims and/or cost data that are so abnormal that they skew the resulting geometric mean per diem costs. For example, we found claims with excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. For an outpatient program like the PHP, which does not incur room and board costs such as an inpatient stay would, these costs per day were excessive. In addition, we found some CMHCs had very low costs per day (less than $25 per day). We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC PHP services. Further analysis of the data confirmed that there were a few providers with extreme cost per day values, which led us to propose and finalize a ±2 standard deviation trim on CMHC costs per day.

During our claims and cost data analysis, we also found aberrant data from some hospital-based PHP providers. The existing OPPS ±3 standard deviation trim removed very extreme CCRs by defaulting two providers that failed this trim to their overall hospital ancillary CCR. However, the calculation of the ±3 standard deviations used to define the trim was influenced by these two providers, which had extreme CCRs greater than 175. Because these two hospital-based PHP providers remained in the data when we calculated the boundaries of the OPPS ±3 standard deviation trim in the CY 2016 ratesetting, the upper limit of the trim boundaries was fairly high, at 28.3446. As such, some aberrant CCRs were not trimmed out, and still had high values ranging from 6.3840 to 19.996. We note that, as stated in CY 2016 OPPS/ASC proposed rule (80 FR 39242 and 39293) and reiterated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456), OPPS defines a biased CCR as one that falls outside the predetermined ceiling threshold for a valid CCR; using CY 2014 cost report data, that threshold is 1.5.

In order to reduce or eliminate the impact of aberrant data received from a few CMHCs and hospital-based PHP providers in the claims data used for ratesetting, we finalized the application of a ±2 standard deviation trim on cost per day for CMHCs and a CCR>5 hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years (80 FR 70456 through 70459). In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459 through 70460), a cost inversion occurred in the final rule data with respect to hospital-based PHP providers. A cost inversion exists when the Level 1 PHP APC geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost for providing 4 or more services per day. We corrected the cost inversion with an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 hospital-based PHP APC geometric mean per diem costs and decreasing the Level 1 hospital-based PHP APC geometric mean per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between the hospital-based Level 1 PHP APC and the Level 2 PHP APC for partial hospitalization services from CY 2013 through CY 2015.

For a comprehensive description on the background of PHP payment policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70453 through 70455).

B. Proposed PHP APC Update for CY 2017

1. Proposed PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2017, we are proposing to continue to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, as explained in greater detail below, we are proposing to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believe this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459).

a. Proposed Changes to PHP APCs

In this CY 2017 OPPS/ASC proposed rule, we are proposing to combine the existing two-tiered PHP APCs for CMHCs into a single PHP APC and the existing two-tiered hospital-based PHP APCs into a single PHP APC. Specifically, we are proposing to replace existing CMHC PHP APCs 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) and 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) with proposed new CMHC PHP APC 5853 (Partial Hospitalization (3 or More Services Per Day)), and to replace existing hospital-based PHP APCs 5861 (Level 1 Partial Hospitalization (3 services) for Hospital-based PHPs) and 5862 (Level 2 Partial Hospitalization (4 or more services) for Hospital-based PHPs) with proposed new hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). In conjunction with this proposal, we are proposing to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for CMHCs (APC 5851 and APC 5852, respectively) to calculate the proposed geometric mean per diem costs for proposed new PHP APC 5853 for CMHCs, and to combine the geometric mean per diem costs for the existing Level 1 and Level 2 PHP APCs for hospital-based PHPs (APC 5861 and APC 5862, respectively) to calculate the proposed geometric mean per diem costs for proposed new PHP APC 5863 for hospital-based PHPs, for CY 2017 and subsequent years. Further, we are proposing to compute the proposed new CMHC PHP APC 5853 proposed geometric mean per diem costs for partial hospitalization services provided by CMHCs using only CY 2015 CMHC claims data and the most recent cost data, and to compute the proposed hospital-based PHP APC 5863 proposed geometric mean per diem costs for partial hospitalization services provided by hospital-based PHPs using only CY 2015 hospital-based PHP claims data and the most recent cost data. We discuss these computations under section VIII.B.2 of this preamble. The proposed geometric mean per diem costs are shown in Table 19 in section VIII.B.2. of this proposed rule.

b. Rationale for Proposed Changes in PHP APCs

One of the primary reasons for our proposal to replace the existing Level 1 and Level 2 PHP APCs with a single PHP APC, by provider type, is because the proposed new PHP APCs would avoid any further issues with cost inversions, and, therefore, generate more appropriate payment for the services provided by specific provider types. As previously stated, a cost inversion exists when the Level 1 PHP APC geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost for providing 4 or more services per day, and, as we noted in last year's final rule with comment period, we do not believe that it would be reasonable or appropriate to pay more for fewer services provided per day and to pay less for more services provided per day (80 FR 70459 through 70460).

To determine if the issue with hospital-based cost inversions that occurred in the data used for the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459) would continue, we calculated the CY 2017 hospital-based PHP APC geometric mean per diem costs separately for Level 1 and Level 2 partial hospitalization services provided by hospital-based PHPs. After applying our established trims and exclusions, we determined that the CY 2017 Level 1 hospital-based PHP APC geometric mean per diem cost would be $241.08 and the CY 2017 Level 2 hospital-based PHP APC geometric mean per diem cost would be $187.06, which again demonstrates an inversion.

We analyzed the CY 2015 hospital-based PHP claims data used for this CY 2017 proposed rule to determine the source of the inversion between the Level 1 and Level 2 hospital-based PHP APCs geometric mean per diem costs, and found that 13 hospital-based PHPs had high geometric mean per diem costs per day. Two of those providers account for 11.5 percent of Level 1 hospital-based PHP service days, but only 1.9 percent of Level 2 hospital-based PHP service days. Eleven of those 13 providers only reported costs for Level 1 hospital-based PHP service days, which increased the geometric mean per diem costs for the Level 1 hospital-based PHP APC. There also were 3 hospital-based PHP providers with very low geometric mean costs per day that accounted for approximately 28 percent of the Level 2 hospital-based PHP service days, which decreased the geometric mean per diem costs for the Level 2 hospital-based PHP APC. High volume providers heavily influence the cost data, and we believe that the high volume providers with very low Level 2 hospital-based PHP geometric mean per diem costs per day and high volume providers with very high Level 1 hospital-based PHP geometric mean per diem costs per day contributed to the inversion between the hospital-based PHP APCs Level 1 and Level 2 geometric mean per diem costs.

In developing the proposal to collapse the Level 1 and Level 2 PHP APCs into one APC each for CMHCs and hospital-based providers, we reviewed the reasons why we structured the existing PHP APCs into a two-tiered payment distinguished by Level 1 and Level 2 services for both provider types in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693), to determine whether the rationales continued to be applicable. In the CY 2009 OPPS/ASC final rule with comment period, we referenced the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), which noted that a significant portion of PHP service days actually provided fewer than three services to Medicare beneficiaries. In our CY 2009 OPPS/ASC final rule with comment period, we noted that PHP service days that provide exactly three services should only occur in limited circumstances. We were concerned about paying providers a single per diem payment rate when a significant portion of the PHP service days provided 3 services, and believed it was appropriate to pay a higher rate for more intensive service days.

We evaluated the frequency of claims reporting Level 1 and Level 2 PHP service days in Table 17 below to determine if a significant portion of PHP service days only provided exactly 3 services. Table 17 shows that the frequency of claims reporting PHP service days providing exactly 3 services (Level 1 services) has decreased greatly from 73 percent of CMHC PHP service days in the CY 2009 rulemaking to 4 percent of CMHC PHP service days in this CY 2017 proposed rulemaking, and from 29 percent of hospital-based PHP service days in the CY 2009 rulemaking to 12 percent of hospital-based PHP service days in this CY 2017 proposed rulemaking. Level 1 PHP service days now represent a small portion of PHP service days, particularly for CMHCs, as shown in Table 17 below. Based on this decline in the frequency of claims reporting Level 1 service days, we believe that the need for the PHP APC Level 1 and Level 2 payment tiers that was present in CY 2009 no longer exists. The utilization data in Table 17 indicate that for the CY 2017 rulemaking year, the Level 2 CMHC PHP service days and the hospital-based PHP Level 2 service days are 96 percent and 88 percent, respectively. Because Level 1 service days are now less common for both provider types, we believe it is no longer necessary to pay a higher rate when 4 or more services are provided compared to when only 3 services are provided. Our proposed new PHP APCs 5853 and 5863 are based on cost data for 3 or more services per day (by provider type). Therefore the combined cost data used to derive proposed new PHP APCs 5853 and 5863 result in appropriate per diems based on costs for providing 3 or more services per day.

TABLE 17—UTILIZATION OF PHP LEVEL 1 DAYS (PROVIDING EXACTLY 3 SERVICES PER DAY) AND PHP LEVEL 2 DAYS (PROVIDING 4 OR MORE SERVICES PER DAY), FROM CY 2007 THROUGH CY 2015 CLAIMS

Rulemaking year	Claims year	CMHC Level 1 days (%)	CMHC Level 2 days (%)	Hospital-based PHP Level 1 days (%)	Hospital-based PHP Level 2 days (%)
CY 2009	CY 2007	73	27	29	71
CY 2010	CY 2008	66	34	25	75
CY 2011	CY 2009	2	98	18	82
CY 2012	CY 2010	2	98	19	81
CY 2013	CY 2011	3	97	11	89
CY 2014	CY 2012	4	96	11	89
CY 2015	CY 2013	6	94	11	89
CY 2016	CY 2014	5	95	11	89
CY 2017	CY 2015	4	96	12	88

When we implemented the PHP APCs Level 1 and Level 2 payment tiers in our CY 2009 rulemaking, we noted that we wanted to provide PHPs with flexibility in scheduling patients. Both the industry and CMS recognized that there may be limited circumstances when it is appropriate for PHPs to receive payment for days when exactly 3 units of service are provided (73 FR 68688 through 68689). Allowing PHPs to receive payment for a Level 1 service day where exactly 3 services are provided gives PHPs some flexibility in scheduling their patients. Our proposal to replace the existing two-tiered PHP APCs with proposed new PHP APCs 5853 and 5863 would provide payment for providing 3 or more services per day by CMHCs and hospital-based PHPs, respectively. Therefore, this flexibility in scheduling remains.

Another primary reason for proposing to replace the Level 1 and Level 2 PHP APCs with a single PHP APC, by provider type, is the decrease in the number of PHPs, particularly CMHCs. With a small number of providers, data from large providers with a high percentage of all PHP service days and unusually high or low geometric mean costs per day will have a more pronounced effect on the PHP APCs geometric mean per diem costs, skewing the costs up or down. That effect would be magnified by continuing to split the geometric mean per diem costs further by distinguishing Level 1 and Level 2 PHP services. Creating a single PHP APC for each provider type providing 3 or more partial hospitalization services per day should reduce these cost fluctuations and provide more stability in the PHP APC geometric mean per diem costs.

We also note that our proposal to replace the existing Level 1 and Level 2 PHP APCs by provider type with a single PHP APC for each provider type is permissible under the applicable statute and regulatory provisions. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. Moreover, the language that follows paragraph (t)(2) of section 1833 of the Act provides that, for purposes of subparagraph (B), items and services within a group shall not be treated as comparable with respect to use of resources if the highest mean cost for an item or services is more than two times greater than the lowest mean cost for an item or service within the group, with some exceptions. Section 419.31 of our regulations implements this statutory provision, providing that CMS classify outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. We believe our proposal to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is supported by the statute and regulations and will continue to pay for partial hospitalization services appropriately based upon actual provider costs.

Both of the existing Level 1 and Level 2 PHP APCs are comprised of services described by the same HCPCS codes. Therefore, the types of services provided under the two payment tiers are the same. The difference is in the quantity of the services provided, where the Level 1 PHP APCs provide for payment for providing exactly 3 services per day, while the Level 2 PHP APCs provide for payment for providing 4 or more services per day. Because the difference in the Level 1 and the Level 2 PHP APCs is in the quantity of the services provided, we would expect that the resource use (that is, the geometric mean per diem cost) for providing partial hospitalization services under Level 1 would represent approximately 75 percent or less of the resource use for providing partial hospitalization services under Level 2, by provider type. Table 18 shows a clear trend for hospital-based PHPs, where the geometric mean per diem costs for providing Level 1 partial hospitalization services have approached the geometric mean per diem costs for providing Level 2 partial hospitalization services, until they exceed the geometric mean per diem costs for providing Level 2 partial hospitalization services beginning in CY 2016. As the percentages in Table 18 approach 100 percent, the Level 1 and the Level 2 PHP APC geometric mean per diem costs become closer to each other, demonstrating similar resource use. The trend is less clear for CMHCs, but the data still show the cost difference between the two tiers narrowing, except in CY 2016. We are not sure why the cost difference is wider among CMHCs in CY 2016 and welcome public comments that can help explain the difference.

TABLE 18—TRENDS IN LEVEL 1 PER DIEM COSTS AS A PERCENTAGE OF LEVEL 2 PER DIEM COSTS

	CY 2013 (%)	CY 2014 (%)	CY 2015 (%)	CY 2016 (%)	CY 2017 (%)
CMHCs—Level 1 PHP APC per diem costs/Level 2 PHP APC per diem costs	77.5	88.6	84.4	66.1	85.5
Hospital-based PHPs—Level 1 PHP APC per diem costs/ Level 2 PHP APC per diem costs	79.2	89.0	91.6	* 110.0	* 128.9

* Cost inversions occurred with the Level 1 PHP APC per diem costs exceeding the Level 2 PHP APC per diem costs.

We evaluated the provision of more costly individual therapy in our CY 2017 analyses to determine if there were differences in its provision for PHP APC Level 1 service days compared to PHP APC Level 2 service days, by provider type, because this could affect our expected difference in resource use (that is, geometric mean per diem costs) between the two payment tiers. We found that individual therapy was provided in roughly the same proportion under the two payment tiers for hospital-based PHPs (in 1.3 percent of PHP APC Level 1 service days and in 1.5 percent of PHP APC Level 2 service days). However, we found that individual therapy was provided less frequently under the Level 1 CMHC PHP service days than under the Level 2 CMHC PHP service days (2.1 percent versus 5.1 percent). The greater frequency of CMHCs' providing more costly individual therapy under Level 2 PHP service days should increase resource use for the more costly partial hospitalization services provided under Level 2 CMHC PHP service days, widening the cost difference between Level 1 and Level 2 CMHC PHP service days. However, as noted previously, that is not what the data show.

As we have described earlier, the services provided under the Level 1 and Level 2 PHP APC payment tiers are comparable clinically and in terms of resource use. Therefore, based on the authority provided under section 1833(t)(2)(B) of the Act and our regulations at § 419.31(a)(1), and because of the policy concerns noted above, we are proposing to replace the Level 1 and Level 2 PHP APCs, by provider type, with a single PHP APC for each provider type for CY 2017 and subsequent years.

Our proposal to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is designed to continue to pay for partial hospitalization services appropriately based upon actual provider costs. We believe that section 1833(t)(2)(B) of the Act and our regulations at § 419.31(a)(1) provide the Secretary with the authority to classify services that are comparable clinically and in terms of resource use under a single APC grouping, which is the basis for our proposal to replace the existing Level 1 and Level 2 PHP APCs for CMHCs and hospital-based PHPs for providing partial hospitalization services with a single PHP APC for each specific provider type. In addition, we believe that our proposal to combine the PHP APCs two-tiered payment structure by provider type would more appropriately pay providers for partial hospitalization services provided to Medicare beneficiaries and avoid cost inversions in the future. Our proposal to combine the PHP APC payment tiers by provider type also would provide more predictable per diem costs, particularly given the small number of CMHCs and the cost inversions that hospital-based PHPs have experienced. The cost inversions between PHP APC Level 1 and Level 2 service days in the hospital-based PHP claims data and the small number of CMHCs are the two primary reasons for our proposal to replace the two-tiered PHP APCs with a single PHP APC for each provider type. The small percentage of all PHP service days for partial hospitalization services provided under the Level 1 PHP APCs further supports our proposal to replace the two-tiered PHP APCs with a single PHP APC for each provider type. As noted previously, we believe that the need for the PHP APC Level 1 and Level 2 payment tiers that was present in CY 2009 no longer exists.

In summary, we are proposing to create proposed new CMHC PHP APC 5853 to pay CMHCs for partial hospitalization services provided to Medicare beneficiaries for providing 3 or more services per PHP service day to replace existing CMHC PHP APCs 5851 and 5852 for CY 2017 and subsequent years. We also are proposing to create proposed new hospital-based PHP APC 5863 to pay hospital-based PHPs for partial hospitalization services provided to Medicare beneficiaries for providing 3 or more services per PHP service day to replace existing hospital-based PHP APCs 5861 and 5862 for CY 2017 and subsequent years. We discuss the proposed geometric mean per diem cost for proposed new CMHC APC 5853 and the proposed geometric mean per diem cost for proposed new hospital-based PHP APC 5863 in section VIII.B.2. of this proposed rule.

If our CY 2017 proposals are implemented, we would pay both CMHCs and hospital-based PHP providers the same payment rate for providing 3 partial hospitalization services in a single service day as is paid for providing 4 or more services in a single service day by the specific provider type. We remind providers that because PHP services are intensive outpatient services, our regulations at § 410.43(c)(1) require that PHPs provide each beneficiary at least 20 hours of services each week. We reiterate that this 20 hour per week requirement is a minimum requirement, and have noted in multiple prior OPPS/ASC final rules with comment periods that a typical PHP program would include 5 to 6 hours per day (70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687). We want providers to continue to have flexibility in providing PHP services, and we will continue to monitor the utilization of providing 3 services per service day for those limited circumstances when a 3-service day is appropriate. We are considering multiple options for enhancing monitoring of providers to assure that they meet the 20 hours of services per week requirement, and we will communicate how we intend to undertake such enhanced monitoring in subregulatory guidance in the future.

Finally, we are concerned by the low frequency of providing individual therapy, which we noted earlier in this section, and we will be monitoring its provision. We believe that appropriate treatment for PHP patients includes some individual therapy. We encourage providers to examine their provision of individual therapy to PHP patients, to ensure that patients are receiving all of the services that they may need.

c. Alternatives Considered

We considered several alternatives to replacing the Level 1 and Level 2 PHP APCs with a single new APC for each PHP provider type. We investigated whether we could maintain the Level 1 and Level 2 PHP APCs if the PHP APC per diem costs were based upon unit costs. However, the same data issues that affected per diem costs also affected unit costs. The hospital-based unit cost data also were inverted such that a Level 1 service day would be more costly than a Level 2 service day. As we have previously noted, we do not believe that it is appropriate to pay more for providing Level 1 services than for providing Level 2 services because only 3 services are provided during Level 1 service days and 4 or more services are provided during Level 2 service days.

We also considered continuing the two-tiered PHP APC payment structure by provider type, and addressing future cost inversions as they arise. Under this alternative, we could propose to use a default methodology for handling cost inversions by only combining the two-tiered PHP APC structure for the provider type with inverted data, and only for the affected calendar year. However, we believe that it could be confusing if one provider type was paid for PHP services based on a two-tiered payment structure, while the other provider type was paid based on a single APC grouping. We also believe that providers would prefer the predictability of knowing whether they would be paid using a single PHP APC or using two-tiered PHP APCs for Level 1 and Level 2 services.

Another alternative for handling cost inversions could be to apply an equitable adjustment. However, the level of adjustment required would vary depending on the degree of the inversion, which also could fluctuate from year to year. Again, we believe that providers would prefer the predictability afforded by avoiding cost inversions altogether, rather than being subject to an ad hoc adjustment as cost inversions arise.

We considered whether we should adjust our data trims, but we determined that the cause of the cost inversion was not due to providers with aberrantly high CCRs or costs per day. Rather, we believe that the cause of the cost inversion was largely the influence of high volume providers with high (but not inappropriately high) Level 1 service day costs and low (but not inappropriately low) Level 2 service day costs in the CY 2015 hospital-based PHP claims data used for this CY 2017 proposed rule. This suggested that adjusting data trims may not be an effective method for resolving the inversion. Nevertheless, we reconsidered our analysis of the CY 2015 claims data for hospital-based PHPs by testing a stricter trim on hospital-based PHP data using the published upper limit CCR that hospitals use for calculating outliers rather than the existing CCR>5 trim. This test of a stricter CCR trim did not remove the inversion, and as a result, we are not proposing to change the existing CCR>5 trim on hospital-based PHP service days for our CY 2017 ratesetting.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs and Payment Rates

For CY 2017 and subsequent years, generally, we are proposing to follow the detailed PHP ratesetting methodology described in section VIII.B.2.e. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to determine the proposed PHP APCs' geometric mean per diem costs and to calculate the proposed payment rates for the two proposed single hospital-based PHP APC and CMHC APC. However, as discussed in section VIII.B.1. of this preamble, in support of our CY 2017 proposals to establish single PHP APCs for hospital-based PHPs and CMHCs, we are proposing to combine the geometric mean per diem costs for the two existing hospital-based PHP APCs to calculate a proposed geometric mean per diem cost for proposed new PHP APC 5863. Currently, hospital-based PHP service days with exactly 3 service units (based on allowable PHP HCPCS codes) are assigned to Level 1 PHP APC 5861, and hospital-based PHP service days with 4 or more service units (based on allowable PHP HCPCS codes) are assigned to Level 2 PHP APC 5862. Under our CY 2017 proposal, instead of separating the service days among these two APCs, we are proposing to combine the service days so that hospital-based PHP service days that provide 3 or more service units per day (based on allowable PHP HCPCS codes) are assigned to proposed new PHP APC 5863. We then are proposing to continue to follow the existing methodology to its end to calculate the proposed geometric mean per diem cost for proposed new PHP APC 5863. Therefore, the proposed geometric mean per diem cost for proposed new PHP APC 5863 would be based upon actual hospital-based PHP claims and costs for PHP service days providing 3 or more services.

Similarly, we are proposing to combine the geometric mean per diem costs for the two existing CMHC PHP APCs to calculate a proposed geometric mean per diem cost for proposed new CMHC PHP APC 5853. Currently, CMHC PHP service days with exactly 3 service units (based on allowable PHP HCPCS codes) are assigned to Level 1 CMHC PHP APC 5851, and CMHC PHP service days with 4 or more service units (based on allowable PHP HCPCS codes) are assigned to Level 2 CMHC PHP APC 5852. Under our CY 2017 proposal, instead of separating the service days among these two APCs, we are proposing to combine the service days so that CMHC PHP service days that provide 3 or more service units (based on allowable PHP HCPCS codes) are assigned to proposed new PHP APC 5853. We then are proposing to continue to follow the existing PHP ratesetting methodology described in section VIII.B.2.e. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to its end to calculate the proposed geometric mean per diem cost for proposed new PHP APC 5853. Therefore, the proposed geometric mean per diem cost for proposed new PHP APC 5853 would be based upon actual CMHC claims and costs for CMHC PHP service days providing 3 or more services.

To prevent confusion, we refer to the per diem costs listed in Table 17 of this proposed rule as the proposed PHP APC per diem costs or the proposed PHP APC geometric mean per diem costs, and the per diem payment rates listed in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) as the proposed PHP APC per diem payment rates or the proposed PHP APC geometric mean per diem payment rates. The PHP APC per diem costs are the provider-specific costs derived from the most recent claims and cost data. The PHP APC per diem payment rates are the national unadjusted payment rates calculated from the PHP APC per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

We are proposing to apply our established methodologies in developing the geometric mean per diem costs and payment rates under this proposal, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR>5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in our CY 2016 OPPS/ASC final rule with comment period (80 FR 70456 through 70459) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

Prior to calculating the proposed geometric mean per diem cost for proposed new CMHC PHP APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016

OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that our ratesetting is not skewed by providers with extreme data. Under the ±2 standard deviation trim policy, we exclude any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2017 ratesetting, three CMHCs with geometric mean per diem costs per day below the trim's lower limit of $42.83 were excluded from the proposed ratesetting for CY 2017. We also apply the OPPS ±3 standard deviation trim on CCRs to exclude any data from CMHCs with CCRs above or below this range. This trim resulted in the exclusion of one CMHC with a very low CCR of 0.001. Both of these standard deviation trims removed a number of providers from ratesetting whose data would have skewed the calculated proposed geometric mean per diem cost downward.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). In our proposed CY 2017 ratesetting, one CMHC was excluded because it was missing wage index data for all of its service days.

In addition to our trims and data exclusions, before determining the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR (80 FR 70457). In our proposed CY 2017 ratesetting, we identified one CMHC that had a CCR>1. This CMHC's CCR was 1.185 and was defaulted to its appropriate statewide hospital ancillary CCR for proposed CY 2017 ratesetting purposes.

These data preparation steps adjusted the CCR for 1 CMHC and excluded 5 CMHCs, resulting in the inclusion of a total of 46 CMHCs in our CY 2017 ratesetting modeling, and the removal of 643 CMHC claims from the 17,033 total CMHC claims used. We believe that excluding providers with extremely low geometric mean costs per day or extremely low CCRs protects CMHCs from having that data inappropriately skew the calculation of the proposed CMHC PHP APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the PHP APC geometric mean per diem payment rates.

After applying all of the above trims, exclusions, or adjustments, the proposed geometric mean per diem cost for all CMHCs for providing 3 or more services per day (proposed new CMHC PHP APC 5853) is $135.30.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

We followed a data preparation process for hospital-based PHP providers that is similar to that used for CMHCs by applying trims and data exclusions as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 to 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions, there were 404 hospital-based PHP providers in the claims data. For hospital-based PHP providers, we apply a trim on hospital service days when the CCR is greater than 5 at the cost center level. The CCR>5 hospital service day trim removes hospital-based PHP service days that use a CCR>5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excludes CMHC providers that fail the trim, the CCR>5 trim excludes any hospital-based PHP service day where any of the services provided on that day are associated with a CCR>5. Applying this trim removed service days from 8 hospital-based PHP providers with CCRs ranging from 5.8763 to 19.9996. However, all of the service days for these eight hospital-based PHP providers had at least one service associated with a CCR>5, so the trim removed these providers entirely from ratesetting. In addition, the OPPS ±3 standard deviation trim on costs per day removed four providers from ratesetting.

Finally, we excluded 13 hospital-based PHP providers that reported zero daily costs on their claims, in accordance with our PHP ratesetting policy (80 FR 70465). Therefore, we excluded a total of 25 hospital-based PHP providers, resulting in 379 hospital-based PHP providers in the data used for ratesetting. After completing these data preparation steps, we calculated the proposed geometric mean per diem cost for proposed new hospital-based PHP APC 5863 for hospital-based PHP services. The proposed geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (proposed hospital-based PHP APC 5863) is $192.57.

Currently, the Level 2 hospital-based PHP per diem costs serve as the cap for all outpatient mental health services provided in a single service day. If our proposal to replace the existing two-tiered PHP APCs structure with a single APC grouping for these services by specific provider type is finalized, the proposed outpatient mental health cap would be the geometric mean per diem costs for proposed new hospital-based PHP APC 5863.

The proposed CY 2017 PHP APC geometric mean per diem costs for the proposed new CMHC and hospital-based PHP APCs are shown in Table 19 below. The proposed PHP APC payment rates are included in Addendum A to this proposed rule (which is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).

TABLE 19—PROPOSED CY 2017 PHP APC GEOMETRIC MEAN PER DIEM COSTS

Proposed CY 2017 APC	Group title	Proposed PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$135.30
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	192.57

We are inviting public comments on these proposals.

3. PHP Ratesetting Process

While PHP services are part of the OPPS, PHP ratesetting has some unique aspects. To foster understanding and transparency, we provided a detailed explanation of the PHP APC ratesetting process in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467). The OPPS ratesetting process includes various steps as part of its data development process, such as CCR determination and calculation of geometric mean per diem costs, identification of allowable charges, development of the APC relative payment weights, calculation of the APC payment rates, and establishment of outlier thresholds. We refer readers to section II. of this proposed rule and encourage readers to review these discussions to increase their overall understanding of the entire OPPS ratesetting process. We also refer readers to the OPPS Claims Accounting narrative, which is a supporting document to this proposed rule, available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link to this proposed rule to find the Claims Accounting narrative. We encourage CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure that they are following these procedures, which should result in greater accuracy in setting the PHP payment rates.

C. Proposed Outlier Policy for CMHCs

1. Estimated Outlier Threshold

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards the genuine cost of outlier cases, and address situations where charges were being inflated to enhance outlier payments.

We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. Beginning in CY 2004, we designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we also established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599).

In this CY 2017 proposed rule, we are proposing to continue to designate a portion of the estimated 1.0 percent outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2017, excluding outlier payments. CMHCs are projected to receive 0.03 percent of total OPPS payments in CY 2017, excluding outlier payments. As we do for each rulemaking cycle, we have updated the CMHC CCRs and claims data used to model the PHP payments rates. This results in CMHC outliers being paid under limited circumstances associated with costs from complex cases, rather than as a substitute for the standard PHP payment to CMHCs. Therefore, we are proposing to designate less than 0.01 percent of the estimated 1.0 percent outlier threshold for CMHCs.

Based on our simulations of CMHC payments for CY 2017, in this proposed rule, we are proposing to continue to set the cutoff point for CY 2017 at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year, which for CY 2017 is the proposed payment rate for proposed new CMHC PHP APC 5853. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2017, we are proposing to continue to pay 50 percent of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2017, if a CMHC's cost for partial hospitalization services paid under proposed new CMHC PHP APC 5853 exceeds 3.4 times the proposed payment rate for proposed new CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the payment rate for proposed new CMHC PHP APC 5853.

In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, in this section, we are proposing to continue to calculate our CMHC outlier threshold and CMHC outlier payments according to our established policies.

2. Proposed CMHC Outlier Cap

Prior to receipt of CY 2015 preliminary claims data, we analyzed CY 2014 CMHC final claims data and found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. While many CMHCs had little or no outlier payments, three CMHCs had very high charges for their CMHC services, which resulted in their collecting large outlier payments that exceeded their total per diem payments. CMHC total per diem payments are comprised of the Medicare CMHC total per diem payments and the beneficiary share of those per diem payments. In total, Medicare paid CMHCs $6.2 million in outlier payments in CY 2014, which was 36 percent of all CMHC total per diem payments. Contrast that 36 percent with the OPPS outlier threshold of 1 percent of total OPPS payments (with the CMHC threshold being a fraction of that 1 percent, based on the percentage of projected per diem payments to CMHCs under the OPPS). In CY 2014, three CMHCs accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments.

When a CMHC's outlier payments approach or exceed its total per diem payments, it suggests that outlier payments are not being used as intended for exceptional high cost patients, but instead as a routine supplement to the per diem payment because outlier payments are being made for nearly all patients. The OPPS outlier policy is intended to compensate providers for treating exceptionally resource-intensive patients. As we noted in our CY 2004 OPPS/ASC final rule with comment period (68 FR 63470), outlier payments were never intended to be made for all patients and used as a supplement to the per diem payment amount. Sections 1833(t)(5)(A) and (B) of the Act specify that outlier payments are to approximate the marginal cost of care when charges, adjusted to cost, exceed a cutoff point established by the Secretary. As stated previously, for CMHCs, that cutoff point is 3.4 times the highest CMHC APC payment rate (PHP APC 0173). In the CY 2014 claims, that meant a CMHC was eligible for an outlier payment for a given day if the cost for that day was greater than 3.4 times CMHC APC 0173 rate for Level II services, or 3.4 times $111.73, which equals $379.88 before wage adjustment.

We examined the total average cost per day for the three CMHCs with outlier payments that were more than 100 percent of their regular payments.

In CY 2014, these three CMHCs had a total average cost per day of $1,065, which exceeded the FY 2014 daily payment rate for inpatient psychiatric care of $713.19. We do not believe that the cost of a day of intensive outpatient CMHC services, which usually comprises 4 hours of services (mostly group therapy), should equal or exceed the cost of a 24-hour period of inpatient care, which includes 24-hour nursing care, active psychiatric treatment, room and board, drugs, and laboratory tests. Because the outpatient PHP daily rate includes payment for fewer items and services than the inpatient psychiatric facility daily rate, we believe that the cost of a day of outpatient PHP care should be significantly less than the cost of a day of inpatient psychiatric care. Therefore, we believe that those three CMHCs with total average cost per day of $1,065 demonstrated excessive outlier payments.

We believe that these excessive outlier payments to some CMHCs are the result of inflated costs, which result from artificially inflated charges. Costs are calculated by multiplying charges by the cost-to-charge ratio. The cost-to-charge ratio used for calculating outlier payments has established upper limits for hospitals and for CMHCs (we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) and the Medicare Claims Processing Internet-only Manual, chapter 4, section 10.11.9, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*). Inflated costs, therefore, usually result from inflated charges, and lead to excessive outlier payments. We also believe that these excessive outlier payments do not approximate the marginal cost of care when costs exceed the established cutoff point, as specified in sections 1833(t)(5)(A) and (B) of the Act. The resulting outlier payments would be inappropriate. We are entrusted with paying CMHCs that are participating in Medicare accurately. Therefore, outlier payments resulting from inflated costs need to be addressed. We also are concerned that if these CMHCs continue this pattern of inflated charges for partial hospitalization services, CMHCs will continue to receive a disproportionate share of outlier payments compared to other OPPS providers that do not artificially inflate their charges, thereby limiting outlier payments for truly deserving cases.

At this point in time, and based on our available claims data, we chose to apply 30 percent of total per diem payments as a cutoff point for reasonable outlier payments. In the CY 2014 claims data, the average charge per day for the 3 CMHCs that received outlier payments ≥30 percent of their total per diem payments was $3,233, which was nearly 8 times greater than the average charge per day for the CMHCs that received outlier payments <30 percent of their total per diem payments. In our review of CY 2015 claims data for this CY 2017 rulemaking, the average charge per day for the CMHCs that received outlier payments ≥30 percent of their total per diem payments was $1,583, which was more than 3 times greater than the average charge per day for the CMHCs that received outlier payments <30 percent of their total per diem payments.

In our review of CY 2015 claims data for this CY 2017 rulemaking, Medicare paid CMHCs $3.2 million in outlier payments, with over 99 percent of those payments made to 4 CMHCs. These outlier payments were 26 percent of all CMHC total per diem payments, and ranged from 39 percent to 179 percent of the individual CMHC's total per diem payments. Total outlier payments to CMHCs decreased from $6.2 million in CY 2014 to $3.2 million in CY 2015 because the CMHC that received the largest outlier payments in CY 2014 no longer had outlier payments in CY 2015. This CMHC revised its charge structure downward. However, two additional CMHCs that did not receive outlier payments in CY 2014 began receiving outlier payments in CY 2015 that were ≥30 percent of their total payments, which suggests a growing problem.

Under the current outlier reconciliation process, a MAC will reconcile a CMHC's outlier payments at the time of final cost report settlement if the CMHC's CCR has changed by 0.10 or more and if the CMHC received any outlier payments. This process is described in Section 10.7.2, Chapter 4, of the Medicare Claims Processing Manual, which is available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.* Typically, final cost report settlement occurs within 12 months of the MAC's acceptance of the cost report. However, because cost reports are filed up to 5 months after the CMHC's fiscal year end, CMHC outlier reconciliation can occur more than a year after outlier overpayments are made. Long timeframes between outlier payment and outlier reconciliation at final cost report settlement have also allowed cases with outlier overpayments to continue and to grow. For example, one CMHC with inflated charges in CY 2013 continued to have inflated charges in CY 2014, and received more than double its CY 2013 outlier payments in CY 2014. This CMHC did not receive outlier payments in CY 2015 because it revised its charge structure downward and, therefore, no longer had costs qualifying for outlier payments.

Although efforts geared towards limiting very high outlier payments to CMHCs are occurring, such as the outlier reconciliation process, these efforts typically occur after the outlier payments are made. We would prefer to focus on stopping questionable outlier payments *before* they occur, to avoid the risk that a provider would be unable to repay Medicare after those overpayments occur. Therefore, we considered whether a broader, supplementary policy change to our CMHC outlier payment policy might also be warranted to mitigate possible billing vulnerabilities associated with very high outlier payments, while at the same time ensuring that we adhere to the existing statutory requirements related to covering the marginal cost of care for exceptionally resource-intensive patients. We want to ensure that CMHCs that provide services that represent the cost of care for legitimate high-cost cases are able to continue to receive outlier payments.

Given these program integrity concerns and our longstanding history of introducing CMHC-specific outlier policies when necessary (the CMHC-specific outlier threshold and the CMHC-specific reconciliation process), we are proposing to implement a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC would receive no more than a set percentage of its CMHC total per diem payments in outlier payments. This outlier payment cap would only affect CMHCs, and would not affect other provider types. This outlier payment cap would be in addition to and separate from the current outlier policy and reconciliation policy in effect. We are proposing that the CMHC outlier payment cap be set at 8 percent of the CMHC's total per diem payments. As noted previously, each CMHC's total per diem payments are comprised of its Medicare CMHC total per diem payments plus the total beneficiary share of those per diem payments. If implemented, this proposal would mean that a CMHC's total outlier payments in a calendar year could not exceed 8 percent of its total per diem payments in that year.

To determine this proposed CMHC outlier cap percentage, we performed analyses to model the impact that a variety of cap percentages would have on CMHC outlier payments. We want to ensure that any outlier cap policy would not disadvantage CMHCs with truly high-cost patients that merit an outlier payment, while also protecting the benefit from making payments for outlier cases that exceed the marginal cost of care. We used CY 2015 preliminary claims data to perform a detailed impact analysis of CMHC outlier payments. We will not have final CY 2015 claims data until after this proposed rule is published, but we will update this analysis using final claims data for our CY 2017 OPPS/ASC final rule with comment period. Out of 51 CMHCs with paid claims in CY 2015, 9 CMHCs received outlier payments. We separated these 9 CMHCs into 4 CMHCs that received outlier payments ≥30 percent of their total CMHC payments in CY 2015, and 5 CMHCs that received had outlier payments <30 percent of their total CMHC payments in CY 2015.

The 5 CMHCs that received outlier payments that were <30 percent of their total per diem payments received a total of $11,496 in outlier payments. We believe that these 5 CMHCs are representative of the types of CMHCs we are most concerned about that would be disadvantaged with an outlier payment policy that includes a cap at the individual CMHC level. We tested the effects of CMHC outlier caps ranging from 3 percent to 10 percent on these two groups of CMHCs. Our analysis focused on total CMHC per diem payments, total CMHC outlier payments, and percentage reductions in payments if a CMHC outlier payment cap were imposed, as shown in Table 20 below.

TABLE 20—EFFECT OF CMHC OUTLIER CAP SIMULATION ON OUTLIER PAYMENTS

	Simulated outlier payments						
	Total per diem payments	Actual outlier payments	3% cap	5% cap	6% cap	8% cap	10% cap
All 51 CMHCs	12,316,182	3,222,896					
5 CMHCs with Outlier Payments <30 Percent of Total Per Diem Payments	9,471,380	11,496	4,196	6,465	7,599	9,868	12,136
Reduction in Outlier Payments			7,299	5,031	3,896	1,628	0
Percent Reduction							
Number of CMHCs Affected			1	1	1	1	0
4 CMHCs with Outlier Payments ≥30 Percent	2,844,802	3,211,401	85,344	142,240	170,688	227,584	284,480
Reduction in Outlier Payments			3,137,552	3,080,656	3,052,208	2,995,312	2,938,416
Percent Reduction			97.7%	95.9%	95.0%	93.3%	91.5%

Based on CY 2015 preliminary claims data.

Note: Of 51 CMHCs in CY 2015 claims data, 9 received outlier payments; 4 CMHCs of those 9 CMHCs received outlier payments ≥30 percent of their total per diem payments. Two of these 4 CMHCs received outlier payments that were >100 percent of their total per diem payments.

The table above shows that 4 out of the 5 CMHCs that received outlier payments <30 percent of their total per diem payments received outlier payments that were less than 1 percent of their total per diem payments and, therefore, would be unaffected by a CMHC outlier payment cap. The 5th CMHC received outlier payments that were 9.4 percent of its total per diem payments and is the only CMHC that would have been affected by a CMHC outlier payment cap applied at the provider level. The effect on this CMHC is shown under the various cap percentage options. At the 8 percent level, this CMHC's outlier payments would have been reduced by $1,628. A 10-percent cap would have had no effect on this CMHC. The difference in total outlier payments to all CMHCs between the 8 percent and 10 percent cap levels was relatively small (about $58,000).

We also conducted our CMHC outlier cap analysis using final CY 2014 claims data. When we evaluated the effect of the different CMHC provider-level outlier cap percentages on the CMHCs with outlier payments < 30 percent of their total per diem payments, using the final CY 2014 claims data, we found that 5 CMHCs would be affected by an 8 percent cap, and 4 CMHCs would be affected by a 10-percent cap, with a difference in outlier payments of only $4,069. However, an 8-percent cap compared to a 10-percent cap saved more than $37,000 in outlier payments to the CMHCs that were charging excessively (data not shown).

We considered both the CY 2014 and CY 2015 claims data as we sought to balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments by proposing an 8-percent CMHC outlier payment cap. An 8-percent CMHC outlier payment cap would mitigate potential inappropriate outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. The 8-percent cap would have reduced outlier payments to the 3 CMHCs that received outlier payments ≥30 percent of their total per diem payments in CY 2015 by $3.0 million dollars, or 93.3 percent.

Therefore, for CY 2017 and subsequent years, we are proposing to apply a CMHC outlier payment cap of 8 percent to each CMHC's total per diem payments, such that in any given calendar year, an individual CMHC would not receive more than 8 percent of its CMHC total per diem payments in outlier payments. We are inviting public comment on the CMHC provider-level outlier cap percentage.

Our existing outlier reconciliation policy would continue to remain in effect with the proposed CMHC outlier payment cap serving as a complement. We are proposing to revise § 419.43(d) of the regulations by adding a paragraph (7) to require that CMHC outlier payments for the calendar year be subject to a CMHC outlier payment cap, applied at the individual CMHC level, that is, 8 percent of each CMHC's total per diem payments for that same calendar year.

We will continue to monitor the trends in outlier payments and if our proposed CMHC outlier payment cap is implemented, we would also monitor these policy effects. We also would analyze CMHC outlier payments at the provider level, relative to the proposed 8 percent CMHC outlier cap. Finally, we will continue to utilize program integrity efforts, as necessary, for those CMHCs receiving excessive outlier payments.

3. Implementation Strategy for a Proposed 8-Percent Cap on CMHC Outlier Payments

CMS envisions that the proposed 8-percent CMHC cap on outlier payments would be managed by the claims processing system. If the proposed CMHC outlier payment cap is finalized, we would provide detailed information on our implementation strategy through sub-regulatory channels. However, to foster a clearer understanding of the proposed CMHC outlier payment cap, we are providing the following high-level summary of the preliminary approach we envision.

For each CMHC, for a given calendar year, the claims processing system would maintain a running tally of year-to-date (YTD) total CMHC per diem payments (Medicare payments and the beneficiary share) and YTD actual CMHC outlier payments. YTD outlier payments for that calendar year could never exceed 8 percent of YTD CMHC total per diem payments for that CMHC for that calendar year. For example, we could determine whether or not a given outlier payment exceeds the 8-percent cap on a "rolling" basis. Under such an implementation approach, for each CMHC, the claims processing system would maintain a running tally of the YTD total CMHC per diem payments. The claims processing system would ensure that each time an outlier claim for a CMHC is processed, actual outlier payments would never exceed 8 percent of the CMHC's YTD total payments. While a CMHC would receive its per diem payment timely, the outlier portion of the claim would be paid as the CMHC's YTD payments support payment of the outlier. As part of our routine claims processing, we would utilize a periodic review process under which outlier payments that were withheld would subsequently be paid if the CMHC's total payments have increased to the point that its outlier payments can be made. This process would result in additional cash flow to CMHCs. As noted previously, we also would maintain our existing outlier reconciliation policy, which is applied at the time of cost report final settlement if the CMHC's CCR changed by 0.10 or more. With regard to revenue tracking by CMHCs, distinct coding would be used on the CMHC's remittance advice when outlier payments are withheld, assisting receivables accountants in identifying and accounting for the differences between expected and actual payments.

4. Summary of Proposals

In summary, for CY 2017, we are proposing to:

- Continue to designate a portion of the estimated 1.0 percent outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2017, excluding outlier payments;
- Implement an 8-percent cap on CMHC outlier payments at the individual CMHC provider level for CY 2017 and subsequent years;
- Continue to set the cutoff point for CMHC outlier payments in CY 2017 at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year, which for CY 2017 is proposed new CMHC PHP APC 5853; and
- Continue to pay 50 percent of CMHC APC geometric mean per diem costs over the cutoff point in CY 2017.

We believe that these CMHC outlier proposals would minimize the impact of inflated CMHC charges on outlier payments, would result in a better approximation of the marginal cost of care beyond the applicable cutoff point compared to the current process, and better target outlier payments to truly exceptionally high-cost cases. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes (IPO list) that we are proposing to be paid by Medicare in CY 2017 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed Changes to the Inpatient Only (IPO) List

For CY 2017, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using the above-listed criteria, we are proposing to remove the following six codes (four spine procedure codes and two laryngoplasty codes) from the IPO list for CY 2017:

- CPT code 22840 (Posterior non-segmental instrumentation (*e.g.,* Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure));
- CPT code 22842 (Posterior segmental instrumentation (*e.g.,* pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure));
- CPT code 31584 (Laryngoplasty; with open reduction of fracture); and
- CPT code 31587 (Laryngoplasty, cricoid split).

We reviewed the clinical characteristics of the four spine procedure codes and related evidence, including input from multiple physician specialty societies whose members specialize in spine surgery, and determined the four spine procedure codes listed above to be appropriate candidates for removal from the IPO list. These four spine procedure codes are add-on codes to procedures that are currently performed in the HOPD and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we believe these spine procedures satisfy criterion 3 as they are related to codes that we have already removed from the IPO list. Because these four spine procedure codes are add-on codes, in accordance with the regulations at 42 CFR 419.2(b)(18), we are proposing to package them with the associated procedure and assign them status indicator "N."

We also reviewed the clinical characteristics of the two laryngoplasty procedure codes and related evidence, and determined that the two laryngoplasty procedure codes listed above are appropriate candidates for removal from the IPO list because we believe they satisfy criterion 3 listed above: The procedure is related to codes that we have already removed from the IPO list. These two codes are related to and clinically similar to CPT code 21495 (Open treatment of hyoid fracture), which is currently not on the IPO list. We are proposing that the two laryngoplasty procedure codes would be assigned to APC 5165 (Level 5 ENT Procedures) with status indicator "J1."

C. Solicitation of Public Comments on the Possible Removal of Total Knee Arthroplasty (TKA) Procedure From the IPO List

1. Background

Total knee arthroplasty (TKA) or total knee replacement, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)), has traditionally been considered an inpatient surgical procedure. The procedure was placed on the original IPO list in the 2000 OPPS final rule (65 FR 18781). In 2000, the primary factors that were used to determine the assignment of a procedure to the IPO list were as follows: (1) The invasive nature of the procedure; (2) the need for at least 24 hours of postoperative care; and (3) the underlying physical condition of the patient who would require the surgery (65 FR 18443 and 18455). In 2000, the geometric mean average length of stay for the DRG to which an uncomplicated TKA procedure was assigned was 4.6 days, and in 2016, the average length of stay for a current uncomplicated TKA procedure for the MS–DRG is 2.8 days.

Recent innovations have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). In this context, "outpatient" services include both same day outpatient surgery (that is, the patient goes home on the same day that the outpatient surgery was performed) and outpatient surgery that includes one overnight hospital stay for recovery from the surgery. These innovations in TKA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. Patients generally benefit from a shorter hospital stay. Some of these benefits include a likelihood of fewer complications, more rapid recovery, increased patient satisfaction, recovery at home with the assistance of family members, and a likelihood of overall improved outcomes. On the contrary, unnecessary inpatient hospitalization exposes patients to the risk of hospital-acquired conditions such as infections and a host of other iatrogenic mishaps.

Like most surgical procedures, TKA needs to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them would likely be good candidates for an outpatient TKA procedure. On the other hand, patients with severe illnesses aside from their osteoarthritis would more likely require inpatient hospitalization and possibly post-acute care in a skilled nursing facility or other facility. Surgeons who have discussed outpatient TKA procedures with us have emphasized the importance of careful patient selection and strict protocols to optimize outpatient TKA outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery and ambulation.

In the CY 2013 OPPS/ASC proposed rule, we proposed to remove the procedure described by CPT code 27447 from the IPO list (77 FR 45153). We proposed to remove the procedure described by CPT code 27447 from the IPO list because we believed that the procedure could be appropriately provided and paid for as a hospital outpatient procedure for some Medicare beneficiaries, based upon the five evaluation criteria for removal from the IPO list discussed earlier. The public comments we received on the CY 2013 proposal varied. There were several surgeons and other stakeholders who supported the proposal. They believed that, given thorough preoperative screening by medical teams with significant experience and expertise involving knee replacement procedures, the TKA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters discussed recent advances in total knee replacement technology and surgical care protocols, including improved perioperative anesthesia, and expedited rehabilitation protocols, as well as significant enhancements to the postoperative process, such as improvements in pain management, early mobilization, and careful monitoring. These commenters also stated that early preventive intervention for the most common medical complications has decreased the average length of hospital stays to the point that a TKA procedure can now be performed on an outpatient basis in certain cases. The commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing TKA on an outpatient basis will lead to significant enhancements in patient well-being and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction. However, the majority of the commenters disagreed with the CY 2013 proposal and believed that it would be unsafe to perform outpatient TKA for Medicare beneficiaries. (We refer readers to 77 FR 68419 for a discussion of these comments.) After consideration of these public comments, we decided not finalize the proposal, and the procedure described by CPT code 27447 remains on the IPO list.

We also note that not uncommonly we receive questions from the public about the IPO list that lead us to believe that some members of the public may misunderstand certain aspects of the IPO list. Therefore, two important principles of the IPO list must be reiterated at the outset of this discussion. First, just because a procedure is not on the IPO list does not mean that the procedure cannot be performed on an inpatient basis. IPO list procedures must be performed on an inpatient basis (regardless of the expected length of the hospital stay) in order to qualify for Medicare payment, but procedures that are not on the IPO list can be and very often are performed on individuals who are inpatients (as well as individuals who are hospital outpatients and ASC patients). Second, the IPO list status of a procedure has no effect on the MPFS professional payment for the procedure. Whether or not a procedure is on the IPO list is not in any way a factor in the MPFS payment methodology.

2. Discussion of TKA and the IPO List

Since 2000, when the IPO list was established, there have been significant developments in both TKA technique and patient care. The advances in TKA technique and patient care are discussed in general terms above. As noted above, in 2000, the criteria by which procedures were reviewed to determine IPO list assignment were as follows: (1) The invasive nature of the procedure; (2) the need for at least 24 hours of postoperative care; and (3) the underlying physical condition of the patient who would require the surgery. In order to discuss the possibility of removing TKA procedures from the IPO list, we believe it is helpful to explore each of these criteria in turn as they apply to present-day TKA. Then we are asking the public to comment on a list of questions that relate to considering removing TKA from the IPO list in the future.

The first criterion was "the invasive nature of the procedure." We elaborated on this criterion in the 2000 OPPS final rule by stating: "We believe that certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary artery bypass grafting, and laparotomies, indisputably require inpatient care, and therefore are outside the scope of outpatient services" (65 FR 18456). TKA does not invade the brain, heart, or abdomen; instead, like several other outpatient orthopedic surgeries, it is an operation on the knee joint. A similar procedure described by CPT code 27446 (Arthroplasty, knee, condyle and plateau; medical OR lateral compartment) (unicompartmental knee replacement) was removed from the IPO list on January 1, 2002, and also was added to the ASC covered surgical procedures list in 2008. The degree of invasiveness of TKA as compared to other major surgical procedures would not appear to prohibit its removal from the IPO list.

The second IPO list criterion from the 2000 OPPS final rule is "the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged." Currently, for procedures that are not on the IPO list, services furnished to patients requiring 24 hours of postoperative recovery time may be payable as either outpatient services or inpatient services, depending on the condition of the patient. Therefore, the need for at least 24 hours of postoperative recovery time or monitoring in many cases should not require IPO list placement.

The third criterion is "the underlying physical condition of the patient who would require the surgery." For this criterion to be the basis of an IPO list assignment seems to presume a relatively homogeneous and morbid patient population undergoing the surgical procedure. Otherwise, patients with a good underlying physical condition could be considered for outpatient surgery while those with a poor underlying physical condition might be more appropriate for inpatient admission. TKA candidates, although they all have osteoarthritis severe enough to warrant knee replacement, are a varied group in which the anticipated length of hospitalization is dictated more by comorbidities and diseases of other organ systems. Some patients may be appropriate for outpatient surgery while others may be appropriate for inpatient surgery.

3. Topics and Questions for Public Comment

We are seeking public comments on whether we should remove the procedure described by CPT code 27447 from the IPO list from all interested parties, including the following groups or individuals: Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform TKA procedures; hospitals and hospital trade associations; and any other interested stakeholders. We are seeking public comments on any of the topics discussed earlier in addition to the following questions:

1. Are most outpatient departments equipped to provide TKA to some Medicare beneficiaries?
2. Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?
3. Is the procedure described by CPT code 27447 sufficiently related to or similar to the procedure described by CPT code 27446 such that the third criterion listed at the beginning of this section for identifying procedures that may be removed from the IPO list, that is, the procedure under consideration for removal from the IPO list is related to codes that we have already removed from the IPO, is satisfied?
4. How often is the procedure described by CPT code 27447 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?
5. Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of a TKA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?
6. CMS is currently testing two episode-based payment models that include TKA: The Comprehensive Care for Joint Replacement (CJR) Model and the Bundled Payment for Care Improvements (BPCI) Model. These models hold hospitals and, in the case of the BPCI, physicians and postacute care providers, responsible for the quality and cost of an episode of care. Providers participating in the CJR model or BPCI Models 2 and 4 initiate episodes with admission to the hospital of a beneficiary who is ultimately discharged under an included MS–DRG. Both initiatives include MS–DRGs 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) and 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC). Depending on the model, the episode ends 30 to 90 days postdischarge in order to cover the period of recovery for beneficiaries. Episodes include the inpatient stay and all related items and services paid under Medicare Part A and Part B for all Medicare fee-for-service (FFS) beneficiaries, with the exception of certain exclusions.

In the BPCI and CJR models, services are paid on an FFS basis with a retrospective reconciliation for all episodes included in a defined time period (quarterly in BPCI and annually in CJR). At reconciliation, actual spending is compared to a target price. The target price is based on historical episode spending. If CMS were to remove the procedure described by CPT code 27447 from the IPO list and pay for outpatient TKA procedures, the historical episode spending data may no longer be an accurate predictor of episode spending for beneficiaries receiving inpatient TKA procedures. As such, establishing an accurate target price based on historical data would become more complicated. This is because some patients who previously would have received a TKA procedure in an inpatient setting may receive the procedure on an outpatient basis if the procedure is removed from the IPO list.

We are seeking comment on how CMS could modify the CJR and BPCI models if the TKA procedure were to be moved off the IPO list. Specifically, we are seeking comment on how to reflect the shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation processes. Some of the issues CMS faces include the lack of historical data on both the outpatient TKA episodes and the average episode spending for beneficiaries who would continue to receive the TKA procedure on an inpatient basis. Because historically the procedure described by CPT code 27447 has been on the IPO list, there is no claims history for beneficiaries receiving TKA on an outpatient basis. In addition, we are seeking public comment on the postdischarge care patterns for Medicare beneficiaries that may receive an outpatient TKA procedure if it were removed from the IPO list and how this may be similar or different from these beneficiaries' historical postdischarge care patterns. For example, Medicare beneficiaries who are appropriate candidates for an outpatient TKA procedure may be those who, in the past, would have received outpatient physical therapy services as follow-up care after an inpatient TKA procedure. CMS would need to develop a methodology to ensure model target prices account for the potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.

X. Proposed Nonrecurring Policy Changes

A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

1. Background

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physician's services in a hospital setting. When a Medicare beneficiary receives services in an off-campus department of a hospital, the total payment amount for the services made by Medicare is generally higher than the total payment amount made by Medicare when the beneficiary receives those same services in a physician's office. Medicare pays a higher amount because it generally pays two separate claims for these services—one under the OPPS for the institutional services and one under the MPFS for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims, often resulting in significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician's office.

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under section 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered covered OPD services as defined under section 1833(t)(1)(B) for purposes of payment under the OPPS and will instead be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, in this proposed rule, we refer to an "off-campus outpatient department of a provider," which is the term used in section 603, as an "off-campus outpatient provider-based department" or an "off-campus PBD."

As noted earlier, section 603 of Public Law 114–74 made two amendments to section 1833 of the Act—one amending paragraph (t)(1)(B) and the other adding new paragraph (t)(21). The provision amended section 1833(t)(1)(B) by adding a new clause (v), which excludes from the definition of "covered OPD services" applicable items and services (defined in paragraph (t)(21)(A)) that are furnished on or after January 1, 2017 by an off-campus PBD, as defined in paragraph (t)(21)(B). The second amendment added a new paragraph (t)(21), which defines the terms "applicable items and services" and "off-campus outpatient department of a provider," requires the Secretary to establish a new payment policy for such applicable items and services furnished by an off-campus PBD on or after January 1, 2017, provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review on certain determinations and information.

In defining the term "off-campus outpatient department of a provider," section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Public Law 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of "off-campus outpatient department of a provider," for purposes of paragraphs (1)(B)(v) and (21)(B), an off-campus PBD that was billing under subsection (t) with respect to covered OPD services furnished prior to the date of enactment of paragraph (t)(21), that is, November 2, 2015. We are proposing to refer to this exception as providing "excepted" status to certain off-campus PBDs and certain items and services furnished by such excepted off-campus PBDs, which would continue to be paid under the OPPS. Moreover, as noted earlier, because the definition of "applicable items and services" specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of "off-campus outpatient department of a provider" does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at 413.65(a)(2)) from a remote location of a hospital facility, the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 will continue to be paid under the OPPS.

In this proposed rule, we are making a number of proposals to implement section 603 of Public Law 114–74. Broadly, we are proposing to do three things: (1) Define applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services shall instead be made under section 1833(t)(21)(C) of the Act; (2) define off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) establish policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, in this rule, we are proposing policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; establish the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBD and for the items and services furnished by such excepted off-campus PBDs); and describe the applicable payment system for nonexcepted items and services. In addition, we are soliciting public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act.

There is no legislative history on record regarding section 603 of Public Law 114–74. However, the Congressional Budget Office estimated program savings for this provision of approximately $9.3 billion over a 10-year period. In January 2016, we posted a notice on the CMS Web site that informed stakeholders that we expected to present our proposals for implementing section 603 of Public Law 114–74 in the CY 2017 OPPS/ASC proposed rule. Because we had already received several inquiries or suggestions from stakeholders regarding implementation of the section 603 provision, we provided a dedicated email address for stakeholders to provide information they believed was relevant in formulating these proposals. We have considered this stakeholder feedback in developing this proposed rule.

2. Defining Applicable Items and Services and an Off-Campus Outpatient Department of a Provider as Set Forth in Sections 1833(t)(21)(A) and (B) of the Act

a. Background on the Provider-Based Status Rules

Since the beginning of the Medicare program, some hospitals, which we refer to as "main providers," have functioned as a single entity while owning and operating multiple departments, locations, and facilities. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments under the OPPS for services provided at the provider-based facility and may also increase the coinsurance liability of Medicare beneficiaries receiving those services. The current criteria for provider-based status are located in the regulations at 42 CFR 413.65.

When a facility or organization has provider-based status, it is considered to be part of the hospital. The hospital as a whole, including all of its PBDs, must meet all Medicare conditions of participation and conditions of payment that apply to hospitals. In addition, a hospital bills for services furnished by its provider-based facilities and organizations using the CMS Certification Number of the hospital. One type of facility or organization that a hospital may treat as provider-based is an off-campus outpatient department. In order for the hospital to do so, the off-campus outpatient department must meet certain requirements under 42 CFR 413.65, including, but not limited to:

- It generally must be located within a 35-mile radius of the campus of the main hospital;
- Its financial operations must be fully integrated within those of the main provider;
- Its clinical services must be integrated with those of the main hospital (for example, the professional staff at the off-campus outpatient department must have clinical privileges at the main hospital, the off-campus outpatient department medical records must be integrated into a unified retrieval system (or cross reference) of the main hospital), and patients treated at the off-campus outpatient department who require further care must have full access to all services of the main hospital;
- It is held out to the public as part of the main hospital.

Section 603 makes certain distinctions with respect to whether a department of the hospital is "on" campus or "off" campus and also excludes from the definition of "off-campus outpatient department of a provider" a department of a provider within the distance from a remote location of a hospital facility. Below, we provide some details on the definitions of the terms "campus" and "remote locations."

Section 413.65(a)(2) of the regulations defines a "campus" as "[T]he physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS Regional Office, to be part of the provider's campus."

In developing the provider-based rules, CMS also recognized that many hospitals operated fully integrated, though geographically separate, inpatient facilities. While the initial scope of provider-based rulemaking primarily concerned situations with outpatient departments, we believed the policies set forth were equally applicable to inpatient facilities. Therefore, CMS also finalized a regulatory definition for a "remote location of a hospital" at 42 CFR 413.65(a)(2) as "a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term 'remote location of a hospital' does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter."

Under the provider-based rules, we consider these inpatient "remote locations" to be "off-campus," and CMS reiterated this position in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50081 through 50082). Hospitals that comprise several sites at which both inpatient and outpatient care are furnished are required to designate one site as its "main" campus for purposes of the provider-based rules. Thus, any facility not located on that main campus would be considered "off-campus" and must satisfy the provider-based rules in order to be treated by the main hospital as provider-based.

For Medicare purposes, a hospital that wishes to add an off-campus PBD must submit an amended Medicare provider enrollment form detailing the name and location of the provider-based facility within 90 days of adding the new facility to the hospital. In addition, a hospital may ask CMS to make a determination that a facility or organization has provider-based status by submitting a voluntary attestation to its MAC, for final review by the applicable CMS Regional Office, attesting that the facility meets all applicable provider-based criteria in the regulations. If no attestation is submitted and CMS later determines that the hospital treated a facility or organization as provider-based when the facility or organization did not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital and the amount of payments that CMS estimates should have been made for items and services furnished at the facility in the absence of compliance with the provider-based requirements for all cost reporting periods subject to reopening. However, if the hospital submits a complete attestation of compliance with the provider-based status requirement for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider based, but CMS subsequently determines that the facility or organization does not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital since the date the attestation was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

Historically, PBDs billed as part of the hospital and could not be distinguished from the main hospital or other PBDs within the claims data. In CY 2015 OPPS/ASC final rule with comment period (79 FR 66910 through 66914), CMS adopted a voluntary claim modifier "PO" to identify services furnished in off-campus PBDs (other than emergency departments, remote locations and satellite locations of the hospital) to collect data that would help identify the type and costs of services typically furnished in off-campus PBDs. Based on the provision in the CY 2015 OPPS/ASC final rule with comment period, use of this modifier became mandatory beginning in CY 2016. While the modifier identifies that the service was provided in an off-campus PBD, it does not identify the type of PBD in which services were furnished, nor does it distinguish between multiple PBDs of the same hospital. As discussed later in this section, we are soliciting public comments on the type of information that would be needed to identify nonexcepted PBDs for purposes of section 603, although we are not proposing to collect such information for CY 2017.

b. Proposed Exemption of Items and Services Furnished in a Dedicated Emergency Department or by an Off-Campus PBD as Defined at Sections 1833(t)(21)(B)(i)(I) and (II) of the Act (Excepted Off-Campus PBD)

(1) Dedicated Emergency Departments (EDs)

Section 1833(t)(21)(A) of the Act specifies that, for purposes of paragraph (1)(B)(v) and [paragraph [21] of section 1833(t), the term "applicable items and services" means items and services *other* than items and services furnished by a dedicated emergency department (as defined in 42 CFR 489.24(b)). Existing regulations at § 489.24(b) define an ED as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Accordingly, based on existing regulations, an ED may furnish both emergency and nonemergency services as long as the requirements under § 489.24(b) are met. In accordance with section 1833(t)(21)(A) of the Act and regulations at § 489.24(b), we are proposing that all services furnished in an ED, whether or not they are emergency services, would be exempt from application of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, and thus continue to be paid under the OPPS. Moreover, we are proposing to define "applicable items and services" to which sections 1833(t)(1)(B)(v) and (t)(21)(A) of the Act apply to include all items and services not furnished by a dedicated ED as described in the regulations at 42 CFR 489.24(b).

(2) On-Campus Locations

As noted earlier, section 1833 (t)(21)(B)(i) of the Act defines the term "off-campus outpatient department of a provider" for purposes of paragraphs (t)(1)(B)(v) and (t)(21) as a department of a provider (as defined at 42 CFR 413.65(a)(2) as that term is in effect as of November 2, 2015), that is not located on the campus of that provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)). We believe that the statutory language refers to such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of Public Law 114–74. The existing regulatory definition of a "department of a provider" includes both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. We used the existing regulatory definition of a department of a provider as a guide in designing our proposals to implement section 603 of Public Law 114–74.

We are not proposing to change the existing definition of "campus" located at § 413.65(a)(2) of our regulations and believe hospitals can adequately determine whether their departments are on-campus, including by using the current provider-based attestation process described in § 413.65(b) to affirm their on-campus status. Currently, the CMS Regional Offices review provider-based attestations to determine whether a facility is within full compliance of the provider-based rules, and hospitals that ask for a provider-based determination are required to specify whether they are seeking provider-based status for an on-campus or off-campus facility or organization. If a CMS Regional Office determines that a department is not in full compliance with the provider-based rules, hospitals may utilize the reconsideration process described under § 413.65(j) and the administrative appeal process described at 42 CFR part 498. As we gain experience under section 603 of Public Law 114–74, we may consider issuing further guidance regarding provider-based attestations if needed.

In accordance with section 1833(t)(21)(B)(i)(I) of the Act, we are proposing that on-campus PBDs and the items and services provided by such a department would be excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

(3) Within the Distance From Remote Locations

In addition to the statutory exception for off-campus PBDs located on the campus of a provider, section 1833(t)(21)(B)(i)(II) of the Act excepts from the definition of off-campus PBDs those that are not located within the distance (as described in the definition of campus at § 413.65(a)(2)) from a "remote location" (as also defined at § 413.65(a)(2)) of a hospital facility. The "distance" described in the definition of "campus" at § 413.65(a)(2) is 250 yards. While hospitals that operate remote locations are referred to as "multicampus" hospitals, as discussed previously, under current provider-based rules, a hospital is only allowed to have a single "main" campus for each hospital. Therefore, when determining whether an off-campus PBD meets the exception set forth at section 1833(t)(21)(B)(i)(II) of the Act, we are proposing that the off-campus PBD must be located at or within the distance of

250 yards from a remote location of a hospital facility. Hospitals should use surveyor reports or other appropriate documentation to ensure that their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose.

c. Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act

Section 1833(t)(21)(B)(ii) of the Act states that, for purposes of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, the term "off-campus outpatient department of a provider" shall not include a department of a provider (that is, an off-campus PBD) (as so defined) that was billing under this subsection, that is, the OPPS, with respect to covered OPD services furnished prior to November 2, 2015. We are proposing that, as provided in section 1833(t)(21)(B)(ii) of the Act, if an off-campus PBD meets this exception, sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act do not apply to that department or to the types of items and services furnished by that department (to be discussed in greater detail below) that were being billed under the OPPS prior to November 2, 2015.

A major concern with determining the scope of the exception set forth at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act is determining how relocation of the physical location or expansion of services lines furnished at the "excepted" off-campus PBD affects the excepted status of the off-campus PBD itself and the items and services furnished by that excepted off-campus PBD.

We have heard from some providers that they believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted off-campus PBDs billing for covered OPD services furnished before November 2, 2015, and that these excepted departments should remain excepted, regardless of whether they relocate or expand services, or both. These providers noted that the exception for certain off-campus PBDs states that section 1833(t)(21)(B)(ii) of the Act does not include an off-campus PBD (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph. These providers argued that, because the statute does not include a specific limitation on relocation or expansion of services, no limitation should be applied.

Providers also have suggested that off-campus PBDs should be able to relocate and maintain excepted status as long as the structure of the PBD is substantially similar to the PBD prior to the relocation. Some stakeholders have suggested that the criteria for defining substantially similar could be based on maintaining similar personnel, space, patient population, or equipment, or a combination of these factors.

We believe that section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time that Public Law 114–74 was enacted, including those items and services furnished and billed by such a PBD prior to that time. Thus, as noted above, we have developed our proposals in defining the scope of the excepted off-campus PBD and the items and services it furnishes based on the existing regulatory definition of department of a provider, which speaks to both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program and the personnel and equipment needed to deliver the services at that facility.

Below we are making a number of proposals regarding the scope of the exception at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and (t)(21) of the Act. These proposals are made in accordance with our belief that section 603 of Public Law 114–74 is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services.

(1) Relocation of Off-Campus PBDs Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In considering how relocation of an excepted off-campus PBD could affect application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act, we are concerned that if we propose to permit excepted off-campus PBDs to relocate and continue such status, hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, move these practices into the larger relocated facilities, and receive OPPS payment for services furnished by these physicians, which we believe section 603 of Public Law 114–74 intended to preclude.

As previously stated, we believe that section 603 of Public Law 114–74 applies to off-campus PBDs as they existed at the time of enactment and only excepts those items and services that were being furnished and billed by off-campus PBDs prior to November 2, 2015.

After reviewing the statutory authority, and the concerns noted earlier, we are proposing that, for purposes of paragraphs (t)(1)(B)(v) and (t)(21) of section 1833 of the Act, excepted off-campus PBDs and the items and services that are furnished by such departments would no longer be excepted if the excepted off-campus PBD moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015. In the case of addresses with multiple units, such as a multi-office building, the unit number is considered part of the address; in other words, an excepted hospital PBD could not purchase and expand into other units in its building, and remain excepted. Once an excepted off-campus PBD has relocated, we are proposing that both the off-campus PBD itself and the items and services provided at that off-campus PBD would no longer be excepted, that is considered to be an excepted off-campus PBD for which the items and services furnished are covered OPD services payable under the OPPS, and instead, would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act.

Hospitals have expressed concern that there may be instances when an excepted off-campus PBD may need to relocate, including, for example, to meet Federal or State requirements, or due a natural disaster. We recognize that there may be circumstances beyond the hospital's control where an excepted off-campus PBD must move from the location in which it existed prior to November 2, 2015. We are soliciting public comments on whether we should develop a clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital VBP program (as implemented in the FY 2014 IPPS/LTCH PPS final rule; 78 FR 50704) for hospitals struck by a natural disaster or experiencing extraordinary circumstances (under which CMS allows a hospital to request a Hospital VBP Program exception within 90 days of the natural disaster or other extraordinary circumstance) that would allow off-campus PBDs to relocate in very limited situations, and that mitigate the potential for the hospital to avoid application of sections 1833(t)(1)(B)(v), and (t)(21)(C) of the Act. In addition, we are seeking public comments on whether we should consider exceptions for any other circumstances that are completely beyond the control of the hospital, and, if so, what those specific circumstance would be.

(2) Expansion of Clinical Family of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act

We have received questions from some hospitals regarding whether an excepted off-campus PBD can expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. As mentioned earlier in the relocation discussion, we have heard that some providers believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted *departments*, pointing out that the statute is not written with any limiting language and that excepted departments should remain excepted, regardless of whether these departments expand either the number of services or the types of services they provide. Under this interpretation, section 1833(t)(21)(B)(ii) of the Act would limit only the number of excepted off-campus PBDs a hospital can have to the number of off-campus PBDs that were billing Medicare for covered OPD services furnished prior to enactment of Public Law 114–74.

We believe that section 1833(t)(21)(B)(ii) of the Act excepts off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of Public Law 114–74, as guided by our regulatory definition of department of a provider. Thus, we are proposing that the excepted off-campus PBD would be limited to seeking payment under the OPPS for the provision of items and services it was furnishing prior to the date of enactment of section 603 of Public Law 114–74 only. Moreover, we are proposing that items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that is, not payable under the OPPS.

As noted earlier, we believe that the amendments to section 1833(t) of the Act were intended to address items and services furnished at physicians' offices that are converted to hospital off-campus PBDs on or after November 2, 2015 from being paid at OPPS rates. One issue we contemplated in considering how expanded services should affect excepted status is how it could affect payment to physicians' offices purchased *after* the date of enactment of section 603. We are concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe these amendments to section 1833(t) of the Act are intended to address.

After reviewing the statutory authority and the concerns raised by commenters noted above, we are proposing, for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that excepted status of items and services furnished in excepted off-campus PBDs is limited to the items and services (defined as clinical families of services below) such department was billing for under the OPPS and were furnished prior to November 2, 2015. We are proposing that if an excepted off-campus PBD furnishes services from a clinical family of services that it did not furnish prior to November 2, 2015, and thus did not also bill for, these new or expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as described in section X.A.1.c. of this proposed rule. We note that we are proposing not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

In summary, our proposals related to expansion of clinical families of services are as follows: We are proposing that service types be defined by the 19 clinical families of hospital outpatient service types described in Table 21 below. Moreover, we are proposing that if an excepted off-campus PBD furnished and billed for any specific service within a clinical family of services prior to November 2, 2015, such clinical family of services would be excepted and be eligible to receive payment under the OPPS. However, we are proposing that if an excepted off-campus PBD furnishes services from a clinical family of services that such department did not furnish and bill for prior to November 2, 2015, those services would be subject to sections 1833(t) (1)(B)(v) and (t)(21) of the Act in CY 2017 and subsequent years. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for which HCPCS codes map to each clinical family of services. If we add a new HCPCS code or APC in future years, we will provide mapping to these clinical families of services, where relevant.

In addition, we considered, but are not proposing in this proposed rule, to specify a specific timeframe in which service lines had to be billed under the OPPS for covered OPD services furnished prior to November 2, 2015. We are seeking public comment on whether we should adopt a specific timeframe for which the billing had to occur, such as CY 2013 through November 1, 2015.

TABLE 21—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical families	APCs
Advanced Imaging	5523–25, 5571–73, 5593–4.
Airway Endoscopy	5151–55.
Blood Product Exchange	5241–44.
Cardiac/Pulmonary Rehabilitation	5771, 5791.
Clinical Oncology	5691–94.
Diagnostic tests	5721–24, 5731–35, 5741–43.
Ear, Nose, Throat (ENT)	5161–66.
General Surgery	5051–55, 5061, 5071–73, 5091–94, 5361–62.
Gastrointestinal (GI)	5301–03, 5311–13, 5331, 5341.
Gynecology	5411–16.
Minor Imaging	5521–22, 5591–2.
Musculoskeletal Surgery	5111–16, 5101–02.
Nervous System Procedures	5431–32, 5441–43, 5461–64, 5471.
Ophthalmology	5481, 5491–95, 5501–04.
Pathology	5671–74.

TABLE 21—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION—Continued

Clinical families	APCs
Radiation Oncology	5611–13, 5621–27, 5661.
Urology	5371–77.
Vascular/Endovascular/Cardiovascular	5181–83, 5191–94, 5211–13, 5221–24, 5231–32.
Visits and Related Services	5012, 5021–25, 5031–35, 5041, 5045, 5821–22, 5841.

Under our proposal, while excepted off-campus PBDs would not be eligible to receive OPPS payments for expanded clinical families of services, such excepted off-campus PBDs would continue to be eligible to receive OPPS payment for clinical families of services that were furnished and billed prior to that date. We discuss later in this section how we are proposing to pay for expanded items and services that are furnished at excepted off-campus PBDs, that is, are nonexcepted items and services.

We are seeking public comments on these proposals. In addition, we are seeking public comments on our proposed categories of clinical families of services, and our proposal not to limit the volume of services furnished within a clinical family of services that the hospital was billing prior to November 2, 2015.

d. Change of Ownership and Excepted Status

Under current policy, provider-based status is defined as the relationship between a facility and a main provider. If a Medicare-participating hospital, in its entirety, is sold or merges with another hospital, a PBD's provider-based status generally transfers to new ownership as long as the transfer would not result in any material change of provider-based status. A provider-based approval letter for such a department would be considered valid as long as the new owners accepted the prior hospital's provider agreement, consistent with other hospital payment policies.

We have received inquiries regarding whether excepted off-campus PBDs would maintain excepted status if a hospital were purchased by a new owner, if a hospital merged with another provider, or if only an excepted off-campus PBD were sold to another hospital.

We are proposing that excepted status for the off-campus PBD would be transferred to new ownership only if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished by such off-campus PBD would no longer be excepted for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We are proposing that individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status. We are soliciting public comments on these proposals.

e. Comment Solicitation for Data Collection Under Section 1833(t)(21)(D) of the Act

Hospitals are required to include all practice locations on the CMS 855 enrollment form. Beginning in March 2011 and ending in March 2015, in accordance with section 1866(j) of the Act, CMS conducted a revalidation process where all actively enrolled hospitals were required to complete a new CMS 855 enrollment form to (1) initially enroll in Medicare, (2) add a new practice location, or (3) revalidate existing enrollment information.

Collection and retention of Medicare enrollment data have been authorized through a Paperwork Reduction Act notice in the **Federal Register**. The authority for the various types of data to be collected is found in multiple sections of the Act and the Code of Federal Regulations; specifically, in sections 1816, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act, and 42 CFR Chapter IV, Subchapter A.

Sections 1833(t)(21)(A) and (B) of the Act exempt both certain off-campus PBDs and the items and services furnished in certain types of off-campus PBDs from application of sections 1833(t)(1)(B)(v) and (21) of the Act. However, while the Medicare enrollment process requires that a hospital identify the name and address of each of its off-campus PBDs, such departments bill under the CMS Certification Number of the hospital, rather than a separate identifier. Accordingly, at this time, we are unable to automate a process by which we could link hospital enrollment information to claims processing information to identify items and services to specific off-campus PBDs of a hospital. In order to accurately identify items and services furnished by each off-campus PBD (exempt or not) and to actively monitor the expansion of clinical family of services at excepted off-campus PBDs, we are seeking public comments on whether to require hospitals to self-report this information to us (via their MAC) using the authority under section 1833(t)(21)(D) of the Act to collect information as necessary to implement the provision.

Specifically, we are seeking public comments on whether hospitals should be required to separately identify all individual excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing and the clinical families of services (shown earlier in Table 21) that were provided by the excepted off-campus PBD prior to the November 2, 2015 date of enactment. If we were to require hospitals to report this information, we would expect to collect this information through a newly developed form which would be available for download on the CMS Web site.

3. Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Off-Campus PBDs)

a. Background on Medicare Payment for Services Furnished in an Off-Campus PBD

As previously noted, under existing policies, Medicare generally makes two types of payments for items and services furnished in an off-campus PBD: (1) Payment for the items and services furnished by the off-campus PBD (that is, the facility) where the procedure is performed (for example, surgical supplies, equipment, and nursing services); and (2) payment for the physician's professional services in furnishing the service(s).

The first type of payment is made under the OPPS. Items and services furnished in an off-campus PBD are billed using HCPCS codes and paid under the OPPS according to the APC group to which the item or service is assigned. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act generally outlines what are covered OPD services eligible for payment under the OPPS. Sections 1833(t)(1)(B)(i) through (iii) of the Act provide for Medicare payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by community mental health centers (CMHCs)), certain items and services that are furnished to inpatients who have exhausted their Part A benefits or who are otherwise not in a covered Part A stay, and certain implantable items. Section 1833(t)(1)(B)(iv) and new subsection (v) list those items and services that are not covered OPD services and, therefore, not eligible for Medicare payment under the OPPS.

The second type of payment for services furnished in an off-campus PBD is for physicians' services and is made under the MPFS at the MPFS "facility rate." For most MPFS services, Medicare maintains two separate payment rates: One that assumes a payment is also made to the facility (the facility rate); and another that assumes the professional furnishes and incurs the full costs associated with furnishing the service (the nonfacility rate). The MPFS facility rate is based on the relative resources involved in furnishing a service when separate Medicare payment is also made to the facility, usually through an institutional payment system, like the OPPS. The MPFS nonfacility rate, which reflects all of the direct and indirect practice expenses involved in furnishing the particular services, is paid in a variety of settings such as physician offices, where Medicare does not make a separate, institutional payment to the facility.

Under Medicare Part B, the beneficiary is responsible for paying cost-sharing, which is generally about 20 percent of both the OPPS hospital payment amount and the MPFS allowed amount. Because the sum of the OPPS payment and the MPFS facility payment for most services is greater than the MPFS nonfacility payment for most services, there is generally a greater cost to both the beneficiary and the Medicare program for services furnished in facilities paid through both an institutional payment system like the OPPS and the MPFS.

The incentives for hospital acquisition of physician practices and the resultant higher payments for the same types of services have been the topic of several reports in the popular media and by governmental agencies. For example, the Medicare Payment Advisory Commission (MedPAC) stated in its March 2014 Report to Congress that Medicare pays more than twice as much for a level II echocardiogram in an outpatient facility ($453) as it does in a freestanding physician office ($189) (based on CY 2014 payment rates). The report determined that the payment difference creates a financial incentive for hospitals to purchase freestanding physicians' offices and convert them to HOPDs without changing their location or patient mix. (MedPAC March 2014 Report to Congress, Chapter 3.) The Government Accountability Office (GAO) also published a report in response to a Congressional request about hospital vertical consolidation. Vertical consolidation is a financial arrangement that occurs when a hospital acquires a physician practice and/or hires physicians to work as salaried employees. In addition, the Office of Inspector General (OIG) published a report in June 2016 entitled "CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain" (OEI–04–12–00380), in which it highlighted concerns about provider-based status in light of the higher costs to both the Medicare program and Medicare beneficiaries relative to when the same services are furnished in the physician office setting. These types of reports highlight the types of concerns we believe Congress may have been trying to address when it legislated section 603 of Public Law 114–74. As we developed our proposal to implement section 603, we took into consideration the concerns described above, the specific statutory language, and the available discretion found in that statutory language.

As described in detail above and below, section 603 of Public Law 114–74, through amendments to section 1833(t) at paragraphs (1)(B)(v) and (21), provides that items and services furnished by nonexcepted off-campus PBDs and certain items and services furnished by excepted off-campus PBDs are not covered OPD services under the OPPS, and that payment shall be made for those applicable items and services under the applicable payment system if the requirements for such payment are otherwise met. However, the statutory amendments do not reference or define a specific applicable payment system under which payment shall be made.

We have established and maintained institutional Medicare payment systems based on specific statutory requirements and on how particular institutions provide particular kinds of services and incur particular kinds of costs. The rules regarding provider and supplier enrollment, conditions of participation, coverage, payment, billing, cost reporting, and coding vary across these institutional payment systems. While some of the requirements are explicitly described in statute and others are captured in CMS regulatory rules or subregulatory guidance, the requirements are unique to the particular type of institution.

Section 1833(t)(21)(C) of the Act provides for the availability of payment under other payment systems for items and services furnished by nonexcepted off-campus PBDs and for certain items and services furnished by excepted off-campus PBDs that are not covered OPD services under the OPPS (for example, expanded clinical families of services). We refer to these items and services collectively as "nonexcepted items and services." Section 1833(t)(21)(C) of the Act provides that payments for these nonexcepted items and services furnished by an off-campus outpatient department of a provider shall be made under the applicable payment system under Medicare Part B (other than under this subsection, that is OPPS), if the requirements for such payment are otherwise met.

While we intend to provide a mechanism for an off-campus PBD to bill and receive payment for furnishing nonexcepted items and services under an applicable payment system that is not the OPPS, at this time, there is no straightforward way to do that before January 1, 2017. At a minimum, numerous complex systems changes would need to be made to allow an off-campus PBD to bill and be paid as another provider or supplier type. For example, currently, off-campus PBDs bill under the OPPS for their services on an institutional claim, whereas physicians and other suppliers bill under the MPFS on a practitioner claim; and there are numerous systems edits designed to be sure that entities enrolled in Medicare bill for their services only within their own payment systems. The Medicare system that is used to process professional claims (the Multi-Carrier System or "MCS") was not designed to accept nor process institutional OPPS claims. Rather, OPPS claims are processed through an entirely separate system referred to as the Fiscal Intermediary Standard System or "FISS" system. To permit an off-campus PBD to bill under a different payment system than the OPPS would require significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. We are not suggesting these operational issues are insurmountable, but they are multifaceted and will require time and care to resolve. As such, we are not able to propose at this time a mechanism for an off-campus PBD to bill and receive payment for nonexcepted items and services furnished on or after January 1, 2017, under an applicable payment system that is not the OPPS.

As described in greater detail below, in order to begin implementing the requirements of section 603 of Public Law 114–74, we are proposing to specify that the applicable payment system for purposes of section 1833(t)(21)(C) of the Act is the MPFS. While we do not believe there is a way to permit off-campus PBDs to bill for nonexcepted items and services they furnish under the MPFS beginning January 1, 2017, we are actively exploring options that would allow off-campus PBDs to bill for these services under another payment system, such as the MPFS, and be paid at the applicable rate under such system beginning in CY 2018. We are soliciting public comment on the changes that might need to be made to enrollment forms, claim forms, the hospital cost report, as well as any other operational changes that might need to be made in order to allow an off-campus PBD to bill for nonexcepted items and services under a payment system other than the OPPS in a way that provides accurate payments under such payment system and minimizes burden on both providers and Medicare beneficiaries. Accordingly, we intend the policy we are proposing in this proposed rule to be a temporary, 1-year solution until we can adapt our systems to accommodate payment to off-campus PBDs for the nonexcepted items and services they furnish under the applicable payment system, other than OPPS.

b. Proposed Payment for Applicable Items and Services Furnished in Off-Campus PBDs That Are Subject to Sections 1833(t)(1)(B)(v) and (21) of the Act

(1) Definition of "Applicable Payment System" for Nonexcepted Items and Services

In this section, we describe our interpretation and proposed implementation of section 1833(t)(21)(C) of the Act, as it applies to nonexcepted items and services for CY 2017 only. Section 1833(t)(21)(C) of the Act requires that payments for nonexcepted items and services be made under the applicable payment system under Medicare Part B (other than under this subsection; that is, the OPPS) if the requirements for such payment are otherwise met. While section 1833(t)(21)(C) of the Act clearly specifies that payment for nonexcepted items and services shall not be made under subsection (t) of section 1833 (that is, the OPPS), it does not define the term "applicable payment system." In analyzing the term "applicable payment system," we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several other payment systems under which payment is made for similar items and services, such as the ASC payment system, the MPFS, or the CLFS.

As noted above, many off-campus PBDs were initially enrolled in Medicare as freestanding physician practices, and were converted as evidenced by the rapid growth of vertical hospital consolidation and hospital acquisition of physician practices.[4] Before these physician practices were converted to off-campus PBDs, the services furnished in these locations, were paid under the MPFS using an appropriate place of service code that identified the location as a nonfacility setting. This would trigger Medicare payment under the MPFS at the nonfacility rate, which includes payment for the "practice expense" resources involved in furnishing services. Many physician practices that were acquired by a hospital became provider-based to the hospital in accordance with the regulations at 42 CFR 413.65. Once a hospital-acquired physician practice became provider-based, the location became an off-campus PBD eligible to bill Medicare under the OPPS for its facility services, while physicians' services furnished in the off-campus PBD were paid at the facility rate under the MPFS. Because many of the services furnished in off-campus PBDs are identical to those furnished in freestanding physician practices, as discussed later in this section, we are proposing to designate the applicable payment system for the payment of the majority of nonexcepted items and services to be the MPFS. Specifically, we are proposing that, because we currently do not have a mechanism to pay the off-campus PBD for nonexcepted items and services, the physician or practitioner would bill and be paid for items and services in the off-campus PBD under the MPFS at the nonfacility rate instead of the facility rate.

When items and services similar to those often furnished by off-campus PBDs are furnished outside of a setting with an applicable Medicare institutional payment system, Medicare payment is generally made under the MPFS under one of several different benefit categories of Medicare benefit such as physician's services, diagnostic tests, preventive services, or radiation treatment services. Although section 1833(t)(1)(B)(v) of the Act specifically carves out from the definition of covered OPD services those items and services defined at section 1833(t)(21)(A) of the Act furnished by certain off-campus PBDs defined by section 1833(t)(21)(B) of the Act, the amendments to section 1833(t) of the Act do not specify that the off-campus outpatient departments of a provider are no longer considered a PBD part of the hospital. This nuance made it difficult for us to determine how to provide payment for the hospital-based portion of the services under MPFS because, as previously noted, Medicare payment processing systems were not designed to allow these off-campus PBDs to bill for their hospital services under a payment system other than OPPS.

Currently, a hospital (including a PBD) does not meet the requirements to bill under another payment system; that is, a hospital and its departments are enrolled as such in the Provider Enrollment, Chain and Ownership System (PECOS) and may only submit institutional claims for payment of covered OPD services under the hospital OPPS under the CMS Certification Number of the hospital. As explained above, there are several other Medicare payment systems for other types of providers and suppliers. Many of these are designed for particular kinds of institutional settings, are specifically authorized by law, and have their own regulations, payment methodologies, rates, enrollment and billing requirements, and in some cases, cost reporting requirements. While the services furnished in a PBD may be the same or similar to those that are furnished in other sites of service, for Medicare purposes, an off-campus PBD is considered to be part of the hospital that meets the requirements for payment under the OPPS for covered OPD services. There currently is no mechanism for it to be paid under a different payment system. In order to allow an off-campus PBD to bill under the MPFS for nonexcepted items and services, we believe it would be necessary to establish a new provider/supplier type (for nonexcepted off-campus PBDs) that could bill and be paid under the MPFS for nonexcepted items and services using the professional claim. At this time, we are not proposing new mechanisms to allow an off-campus PBD to bill and receive payment from Medicare for nonexcepted items and services as currently enrollment as a hospital based department. However, as described in detail later in this section, we are soliciting comment on changes that would need to be made in order to allow an off-campus PBD to bill for nonexcepted items services it furnishes under a payment system other than the OPPS.

---

[4] The number of vertically consolidated hospitals and physicians increased from 2007 through 2013. Specifically, the number of vertically consolidated hospitals increased from about 1,400 to 1,700, while the number of vertically consolidated physicians nearly doubled from about 96,000 to 182,000. This growth occurred across all regions and hospital sizes, but was more rapid in recent years. (Government Accountability Office; GAO 16–189, December 2015; *http://www.gao.gov/products/GAO-16-189*)

Accordingly, for CY 2017, we are proposing the MPFS to be the applicable payment system for nonexcepted items and services that, but for section 603, would have otherwise been paid under the OPPS; and that payment would be made for applicable nonexcepted items and services to the physician or practitioner under the MPFS at the nonfacility rate because no separate facility payment would be made to the hospital. We note that the hospital may continue to bill for services that are not paid under the OPPS, such as laboratory services.

(2) Definition of Applicable Items and Services and Section 603 Amendment to Section 1833(t)(1)(B) of the Act and Proposed Payment for Nonexcepted Items and Services for CY 2017

(a) Background

Section 1833(t)(21)(A) of the Act defines the term "applicable items and services" for purposes of paragraph (t)(1)(B)(v) and paragraph (t)(21) to mean items and services (other than those furnished by a dedicated emergency department). Paragraph (1)(B)(v) then specifically carves out from the definition of covered OPD services, that is, those applicable items and services that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (t)(21)(B). Thus, such applicable items and services are not eligible for payment under the OPPS because they are not covered OPD services. Under our proposals, this would mean that all items and services furnished by a nonexcepted off-campus PBD and those nonexcepted items and services furnished by an excepted off-campus PBD (collectively references as nonexcepted items and services) are applicable items and services under the statute. Therefore, instead of being eligible for payment under the OPPS as covered OPD services, paragraph (t)(21)(C) requires that, for nonexcepted items and services, payment shall be made under the applicable payment system, other than OPPS, if the requirements for such payment are otherwise met. In other words, the payment requirement under paragraph (t)(21)(C) applies to items and services furnished by nonexcepted off-campus PBDs and for expanded clinical families of services furnished by excepted off-campus PBDs (nonexcepted items and services).

(b) Proposed Payment Policy for CY 2017

In accordance with sections 1833(t)(1)(B)(v) and 1833(t)(21)(C) of the Act, payment for nonexcepted items and services as defined in section X.A.2. of this proposed rule will no longer be made under the OPPS, effective January 1, 2017. Instead, we are proposing that, for items and services for which payment can be made to a billing physician or practitioner under the MPFS, the physician or practitioner furnishing such services in the off-campus PBD would bill under the MPFS at the nonfacility rate. As discussed earlier in this section, we do not believe that, under current systems, an off-campus PBD could be paid for its facility services under the MPFS, but are actively exploring options that would allow for this beginning in CY 2018. Alternatively, an off-campus PBD would have the option to enroll as a freestanding facility or supplier in order to bill for the nonexcepted items and services it furnishes (which is different from billing only for reassigned physicians' services) under the MPFS.

At this time, we are not proposing a change in payment policy under the MPFS regarding these nonexcepted items and services. However, in the CY 2017 MPFS proposed rule, we are proposing to amend our regulations and subregulatory guidance to specify that physicians and nonphysician practitioners furnishing professional services would be paid the MPFS nonfacility rate when billing for such services because there will be no accompanying Medicare facility payment for nonexcepted items and services furnished in that setting. The MPFS nonfacility rate is calculated based on the full costs of furnishing a service, including, but not limited, to space, overhead, equipment, and supplies. Under the MPFS, there are many services that include both a professional component and a technical component. Similarly, there are some services that are defined as either a "professional-only" or "technical-only" service. The professional component is based on the relative resource costs of the physician's work involved in furnishing the service and is generally paid at a single rate under the MPFS, regardless of where the service is performed. The technical component portion of the service is based on the relative resource costs of the nonphysician clinical staff who perform the test, medical equipment, medical supplies, and overhead expenses. When the service is furnished in a setting where Medicare makes a separate payment to the facility under an institutional payment system, the technical component is not paid under the MPFS because the practitioner/supplier did not incur the cost of furnishing the technical component. Rather, it would be paid to the facility under the applicable institutional payment system.

If an off-campus PBD that furnishes nonexcepted items and services wishes to bill Medicare for those services, it could choose to meet the requirements to bill and receive payment under a payment system other than the OPPS by enrolling the off-campus PBD as another provider/supplier type. For example, an off-campus PBD could enroll in Medicare as an appropriate alternative provider or supplier type (such as an ASC or physician group practice). The enrolled provider/supplier would then be able to bill and be paid under the payment system for that type of Medicare enrolled entity. For example, if an off-campus PBD were to enroll as a group practice, it would bill on the professional claim and be paid under the MPFS at the nonfacility rate in accordance with laws and regulations that apply under the MPFS.

We recognize that our proposal to pay under the MPFS for all nonexcepted items and services furnished to beneficiaries may result in hospitals establishing business arrangements with the physicians or nonphysician practitioners who bill under the MPFS. We are interested in public comments regarding the impact of other billing and claims submission rules, the fraud and abuse laws, and other statutory and regulatory provisions on our proposals. Specifically, we are interested in public comments regarding the limitations of section 1815(c) of the Act and 42 CFR 424.73 (the reassignment rules); the limitations of section 1842(n) of the Act and 42 CFR 414.50 (the anti-markup prohibition); the application of section 1877 of the Act and 42 CFR 411.350 through 411.389 (the physician self-referral provisions) to any compensation arrangements that may arise; and the application of section 1128B(b) of the Act (the Federal anti-kickback statute) to arrangements between hospitals and the physicians and other nonphysician practitioners who refer to them. We will consider these laws and regulations as well, and look forward to reviewing public comments on the anticipated impact of these provisions on our proposed policy and any possible future proposals.

We note that there are some services that off-campus departments may furnish that are not billed or paid under the OPPS. For example, although laboratory tests are generally packaged under the OPPS, there are some circumstances in which hospitals are permitted to bill for certain laboratory tests and receive separate payment under the CLFS. These circumstances include:

- Outpatient laboratory tests are the only services provided. If the hospital provides outpatient laboratory tests only and no other hospital outpatient services are reported on the same claim.
- Unrelated outpatient laboratory tests. If the hospital provides an outpatient laboratory test on the same claim as other hospital outpatient services that is clinically unrelated to the other hospital outpatient services (that is, the laboratory test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services and for a different diagnosis than the other hospital outpatient services). We note that this exception is being proposed for deletion for CY 2017. We refer readers to section II.B.3.b.(2) of this proposed rule for a discussion of this policy.
- Molecular pathology laboratory tests and advanced diagnostic laboratory tests (ADLTs) (proposed for CY 2017 in section II.B.3.b.(3) of this proposed rule).
- Laboratory tests that are preventive services.

Under our proposal, if a laboratory test furnished by a nonexcepted off-campus PBD is eligible for separate payment under the CLFS, the hospital may continue to bill for it and receive payment under the CLFS. In addition, a bill may be submitted under the MPFS by the practitioner (or hospital for physicians who have reassigned their benefit), provided that the practitioner meets all the MPFS requirements. Consistent with cost reporting guidance and Medicare Program Reimbursement Manual, Part 1, Chapter 23, Section 2302.8, hospitals should report these laboratory services on a reimbursable cost center on the hospital cost report.

In addition, with respect to partial hospitalization programs (PHP) (intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care), section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a CMHC. Because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, we note that a nonexcepted off-campus PBD is eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. A hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018

For nonexcepted items and services furnished in an off-campus PBD, we are soliciting public comments which we intend to consider in developing a new billing and payment policy proposal for CY 2018. Specifically, we are interested in comments regarding whether an off-campus PBD should be allowed to bill nonexcepted items and services on the professional (not institutional) claim and receive payment under the MPFS, provided the PBD meets all the applicable MPFS requirements. Under this proposal, we envision that the PBD would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participations and regulations governing its provider-based status, but, for payment purposes, the off-campus PBD would be considered a nonhospital setting that is similar to a freestanding physician office or clinic and that is paid the same rate that is paid to freestanding offices or clinics under the MPFS. We note that there are other nonpractitioner entities that bill these kinds of services under the MPFS (for example, Independent Diagnostic Testing Facilities, Radiation Treatment Centers), and we are seeking public comments on whether or not there are administrative impediments for hospitals billing for such services. We are seeking public comments on whether making the necessary administrative changes that would allow the hospital to bill for these kinds of services under the MPFS would provide any practical benefit to the hospitals relative to the current requirements for billing under the MPFS. We also are seeking public comments on other implications or considerations for allowing the hospital to do this, such as how the cost associated with furnishing such services might be reflected on the hospital cost report.

4. Beneficiary Cost-Sharing

Under our proposed policy, payment for most nonexcepted items and services under section 1833(t)(21)(C) of the Act would be made under the MPFS to the physician at the nonfacility rate. As a result, we expect that the beneficiary cost-sharing for such nonexcepted items and services would generally be equal to the beneficiary cost-sharing if the service was provided at a freestanding facility.

5. Summary of Proposals

Under our proposed policy, all excepted off-campus PBDs would be permitted to continue to bill for excepted items and services under the OPPS. These excepted items and services include those furnished in an ED, in an on-campus PBD, or within the distance from a remote location of a hospital facility. In addition, excepted items and services include those furnished by an off-campus PBD that was billing Medicare for covered OPD services furnished prior to November 2, 2015 for all services within a clinical family of services, provided that those services continue to be furnished at the same physical address of the PBD as of November 2, 2015. Items and services furnished in a new off-campus PBD (that is, not billing under the OPPS for covered OPD services furnished prior to November 2, 2015) or new lines of service furnished in an excepted off-campus PBD would not be excepted items and services. An excepted off-campus PBD would lose its status as excepted (that is, the off-campus PBD would be considered a new nonexcepted off-campus PBD) if the excepted off-campus PBD changes location or changes ownership; if the new owners also acquire the main hospital and adopt the existing Medicare provider agreement, the excepted off-campus PBD may maintain its excepted status under the other rules outlined in this proposed rule.

For CY 2017, we are proposing that the MPFS will be the "applicable payment system" for the majority of nonexcepted items and services furnished in an off-campus PBD. Physicians furnishing services in these departments would be paid based on the professional claim and would be paid at the nonfacility rate for services for which they are permitted to bill. Provided it can meet all Federal and other requirements, a hospital continues to have the option of enrolling the nonexcepted off-campus PBD as the type of provider/supplier for which it wishes to bill in order to meet the requirements of that payment system (such as an ASC or group practice).

For CY 2018, we are soliciting public comments on regulatory and operational changes that we could make to allow an off-campus PBD to bill and be paid for its services under an applicable payment system. We will take these comments into consideration in developing a new payment policy proposal for CY 2018.

As we and our contractors conduct audits of hospital billing, we and our contractors will examine whether off-campus PBDs are billing under the proper billing system. We expect hospitals to maintain proper documentation showing what lines of service were provided at each off-campus PBD prior to November 2, 2015, and to make this documentation available to us and our contractors upon request.

6. Proposed Changes to Regulations

To implement the provisions of section 1833(t) of the Act, as amended by section 603 of Public Law 114–74, we are proposing to amend the Medicare regulations by (a) adding a new paragraph (v) to § 419.22 to specify that, effective January 1, 2017, for cost reporting periods beginning January 1, 2017, excluded from payment under the OPPS are items and services that are provided by an off-campus provider-based department of a hospital that do not meet the definition of excepted items and services; and (b) adding a new § 419.48 that sets forth the definition of excepted items and services.

B. Changes for Payment for Film X-Ray

Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1833(t)(16) of the Act by adding new subparagraph (F). New section 1833(t)(16)(F)(i) of the Act provides that, effective for services furnished during 2017 or any subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS (without application of subparagraph (F)(i) and before application of any other adjustment) shall be reduced by 20 percent. New section 1833(t)(16)(F)(ii) of the Act provides that payments for imaging services that are X-rays taken using computed radiography (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be made under the OPPS (without application of subparagraph (F)(ii) and before application of any other adjustment), be reduced by 7 percent, and similarly, if such X-ray services are furnished during CY 2023 or a subsequent year, by 10 percent. New section 1833(t)(16)(F)(iii) of the Act provides that the reductions made under section 1833(t)(16)(F) shall not be considered an adjustment under section 1833(t)(2)(E) of the Act, and shall not be implemented in a budget neutral manner. New section 1833(t)(16)(F)(iv) of the Act instructs the implementation of the reductions in payment set forth in subparagraph (F) through appropriate mechanisms which may include use of modifiers. Below we discuss the proposed implementation of the reduction in payment for imaging services that are X-rays taken using film provided for in section 1833(t)(16)(F)(i) of the Act. We will address the reductions in OPPS payment for imaging services that are X-rays taken using computed radiography technology (including the imaging portion of a service) in future rulemaking.

To implement the provisions of sections 1833(t)(16)(F)(i) of the Act relating to the payment reduction for imaging services that are X-rays taken using film that are furnished during CY 2017 or a subsequent year, in this proposed rule, we are proposing to establish a new modifier to be used on claims, as allowed under the provisions of new section 1833(t)(16)(F)(iv) of the Act. The applicable HCPCS codes describing imaging services that are X-rays taken using film can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing that, beginning January 1, 2017, hospitals would be required to use this modifier on claims imaging services that are X-rays taken using film. The use of this proposed modifier would result in a 20-percent payment reduction for an imaging service that is an X-ray service taken using film, as specified under section 1833(t)(16)(F)(i) of the Act, of the determined OPPS payment amount (without application of subparagraph (F)(i) and before any other adjustments under section 1833(t) of the Act). For further discussion regarding the budget neutrality of the payment reductions under section 1833(t)(16)(F) of the Act, we refer readers to section XX.A.3. of this proposed rule.

C. Changes to Certain Scope-of-Service Elements for Chronic Care Management (CCM) Services

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70450 through 70453), we finalized the CCM scope of service elements (as described in the CY 2015 MPFS final rule with comment period (79 FR 67721)) required in order for hospitals to bill and receive OPPS payment for furnishing CCM services. These scope-of-service elements are the same as those required for CCM under the MPFS. In the CY 2017 MPFS proposed rule, we are proposing some minor changes to certain CCM scope of service elements. We are proposing that these proposed changes also would apply to CCM services furnished to hospital outpatients under the OPPS. All of the fundamental scope-of-service requirements are remaining intact. An example of these proposed minor changes are that the electronic sharing of care plan information would need to be timely but not necessarily on a 24 hour a day/7 days week basis, as is currently required. We refer readers to the CY 2017 MPFS proposed rule for a detailed discussion of the proposed changes to the scope of service elements for CCM.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access of Medicare Act of 2014 (PAMA, Pub. L. 113–93) amended section 1834 of the Act by adding paragraph (q) which directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 MPFS final rule with comment period (80 FR 71102 through 71116) addressed the initial component of the Medicare AUC program, including specifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations. The regulations governing the Medicare AUC program are codified at 42 CFR 414.94. The program's criteria and requirements were established and are being updated as appropriate through the MPFS rulemaking process. While the MPFS is the most appropriate vehicle for this practitioner-based program, we note that ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims, for all applicable advanced diagnostic imaging services paid under the MPFS, the OPPS, and the ASC payment system. The CY 2017 MPFS proposed rule includes proposed requirements and processes for the second component of the Medicare AUC program, which is the specification of qualified clinical decision support mechanisms (CDSMs) under the program. The CDSM is the electronic tool through which the ordering practitioner consults AUC. It also proposes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. We refer readers to the CY 2017 MPFS proposed rule for further information.

XI. Proposed CY 2017 OPPS Payment Status and Comment Indicators

A. Proposed CY 2017 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the payment status indicators and their definitions that we are proposing for CY 2017 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed CY 2017 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

For CY 2017, we are proposing to revise the current definition of status indicator "E" by creating two status indicators, "E1" and "E2," to replace status indicator "E." Status indicator "E1" would be specific to items and services not covered by Medicare and status indicator "E2" would be exclusive to those items and services for which pricing information or claims data are not available.

B. Proposed CY 2017 Comment Indicator Definitions

For CY 2017 OPPS, we are proposing to use four comment indicators. Three of these comment indicators, "CH," "NI," and "NP," are in effect for CY 2016 and we are proposing to continue their use in CY 2017. In this proposed rule, we are proposing to create new comment indicator "NC" that would be used in the final rule to flag the HCPCS codes that were assigned to comment indicator "NP" in the proposed rule. Codes assigned the "NC" comment indicator in the final rule will not be subject to comments to the final rule. We believe that this new comment indicator "NC" will help hospitals easily identify new HCPCS codes that will have a final payment assignment effective January 1, 2017. The proposed CY 2017 OPPS comment indicators are as follows:

- "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- "NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- "NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.
- "NC"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.

The definitions of the OPPS comment indicators for CY 2017 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70474 through 70502).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure ("overnight stay"). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79

FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). CMS releases new and revised Level II HCPCS codes and recognizes the release of new and revised CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. CMS releases new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payment and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes; however, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2017 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2017 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2017 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2018 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70371 through 70372) on the new and revised Category I and III CPT and Level II HCPCS codes that were effective January 1, 2016. We also sought public comments in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70371) on the new and revised Level II HCPCS codes effective October 1, 2015 or January 1, 2016. These new and revised codes, with an effective date of October 1, 2015 or January 1, 2016, were flagged with comment indicator "NI" in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2016 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2017 OPPS/ASC final rule with comment period.

In Table 22 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 22—COMMENT AND FINALIZATION TIMEFRAMES FOR CY 2017 FOR NEW AND REVISED CATEGORY I AND III CPT CODES AND LEVEL II HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2016	Level II HCPCS Codes	April 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
July 1, 2016	Level II HCPCS Codes	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2016	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.
October 1, 2016	Level II HCPCS Codes	October 1, 2016	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.
January 1, 2017	Level II HCPCS Codes	January 1, 2017	CY 2017 OPPS/ASC final rule with comment period.	CY 2018 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes	January 1, 2017	CY 2017 OPPS/ASC proposed rule.	CY 2017 OPPS/ASC final rule with comment period.

Note: In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. We refer readers to section XII.A.3. of this CY 2017 OPPS/ASC proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2016 and July 2016 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2016 and July 2016 CRs, we made effective for April 1, 2016 and July 1, 2016, respectively, a total of 20 new Level II HCPCS codes and 9 new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2016 OPPS/ASC final rule with comment period.

In the April 2016 ASC quarterly update (Transmittal 3478, CR 9557, dated March 11, 2016), we added 10 new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 23 below lists the new Level II HCPCS codes that were implemented April 1, 2016, along with their proposed payment indicators for CY 2017.

In the July 2016 ASC quarterly update (Transmittal R3531CP, CR 9668, dated May 27, 2016), we added nine new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 24 below lists the new Level II HCPCS codes that were implemented July 1, 2016. The proposed payment rates, where applicable, for these April and July codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2016 quarterly update CR, we also implemented ASC payment for nine new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2016. These codes are listed in Table 25 below, along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT codes and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2016 and July 2016 through the quarterly update CRs, as listed in Tables 23, 24, and 25 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2017 OPPS/ASC final rule with comment period.

TABLE 23—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2016

CY 2016 HCPCS code	CY 2016 long descriptor	Proposed CY 2017 payment indicator
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U	K2
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U	K2
C9461	Choline C 11, diagnostic, per study dose	K2
C9470	Injection, aripiprazole lauroxil, 1 mg	K2
C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	K2
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K2
C9473	Injection, mepolizumab, 1 mg	K2
C9474	Injection, irinotecan liposome, 1 mg	K2
C9475	Injection, necitumumab, 1 mg	K2
J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg	K2

TABLE 24—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 HCPCS code	CY 2016 long descriptor	Proposed CY 2017 payment indicator
C9476	Injection, daratumumab, 10 mg	K2
C9477	Injection, elotuzumab, 1 mg	K2
C9478	Injection, sebelipase alfa, 1 mg	K2
C9479	Instillation, ciprofloxacin otic suspension, 6 mg	K2
C9480	Injection, trabectedin, 0.1 mg	K2
Q9981	Rolapitant, oral, 1 mg	K2
Q5102	Injection, infliximab, biosimilar, 10 mg	K2
Q9982 *	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	K2
Q9983 **	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	K2

* HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) was deleted on June 30, 2016, and replaced with HCPCS code Q9982 effective July 1, 2016.

** HCPCS code C9458 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries) was deleted on June 30, 2016, and replaced with HCPCS code Q9983 effective July 1, 2016.

TABLE 25—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016

CY 2016 CPT code	CY 2016 long descriptor	Proposed CY 2017 payment indicator
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure).	N1
0438T *	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.	G2
0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure).	N1
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	G2
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	G2
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve).	G2
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	G2
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral.	N1
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral.	N1

* HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies) was deleted on June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.

3. Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which We Are Accepting Comments in This CY 2017 Proposed Rule

For new and revised CPT codes effective January 1 that are received in time to be included in the proposed rule, we are proposing APC and status indicator assignments. We will accept comments and finalize the APC and status indicator assignments in the OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in the OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 2017 ASC update, the new and revised CY 2017 Category I and III CPT codes will be effective on January 1, 2017 and can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS Web site). The new and revised CY 2017 Category I and III CPT codes are assigned to new comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2017 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled "CY 2017 OPPS/ASC Proposed Rule 5-Digit Placeholder Code," to this proposed rule. The final CPT code numbers will be included in the CY 2017 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator "NP."

In summary, we are soliciting public comments on the proposed CY 2017 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2017. The

CPT codes are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2017 OPPS/ASC final rule with comment period. The proposed payment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS Web site).

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year.

For CY 2017, we are proposing to continue our established policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to those new and revised Level II HCPCS codes that are effective October 1 and January 1 to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the Level II HCPCS codes that will be effective October 1, 2016 and January 1, 2017 would be flagged with comment indicator "NI" in Addendum B to the CY 2017 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2017. We will invite public comments in the CY 2017 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes that will be finalized in the CY 2018 OPPS/ASC final rule with comment period.

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2017 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2015 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator "G2" (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2016, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2," "P3," or "R2" in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70480 through 70482).

Our review of the CY 2015 volume and utilization data resulted in our identification of one covered surgical procedure, CPT code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), that we believe meets the criteria for designation as office-based. The data indicate that this procedure is performed more than 50 percent of the time in physicians' offices, and we believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT code that we are proposing to permanently designate as office-based for CY 2017 is listed in Table 26 below.

TABLE 26—ASC COVERED SURGICAL PROCEDURE PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2017

CY 2017 CPT code	CY 2017 long descriptor	CY 2016 ASC payment indicator	Proposed CY 2017 ASC payment indicator *
0377T	Anoscopy with directed submucosal injection of bulking agent for fecal incontinence Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	G2	R2

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

We also reviewed CY 2015 volume and utilization data and other information for eight procedures finalized for temporary office-based status in Tables 64 and 65 in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70480 through 70482). Of these eight procedures, there were very few claims in our data or no claims data for all eight procedures: CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); CPT code 0402T (Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)); CPT code 10030 (Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity, abdominal wall, neck), percutaneous); CPT code 64461 (Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed); CPT code 64463 (Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)); CPT code 65785 (Implantation of intrastromal corneal ring segments); CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (for example, retinopathy of prematurity), photocoagulation or cryotherapy); and CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies). Consequently, we are proposing to maintain the temporary office-based designations for these eight codes for CY 2017. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2017 in Table 27 below. The procedures for which the proposed office-based designations for CY 2017 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 27—PROPOSED CY 2017 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2016 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2017 CPT code	CY 2017 long descriptor	CY 2016 ASC payment indicator *	CY 2017 ASC proposed payment indicator **
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *	R2 **
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2 *	R2 **
10030	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity abdominal wall, neck), percutaneous.	P2 *	P2 **
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	P3 **
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3 *	P3 **
65785	Implantation of intrastromal corneal ring segments	R2 *	P2 **
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.,* retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 **
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2 *	R2 **

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

For CY 2017, we are proposing to designate certain new CY 2017 codes for ASC covered surgical procedures as temporary office-based, displayed in Table 28 below. After reviewing the clinical characteristics, utilization, and volume of related codes, we determined that the procedures described by these new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we are proposing to make the office-based designations temporary rather than permanent and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designations for CY 2017 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

TABLE 28—PROPOSED CY 2017 PAYMENT INDICATORS FOR NEW CY 2017 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

Proposed CY 2017 OPPS/ASC proposed rule 5-digit CMS placeholder code ***	CY 2017 long descriptor	Proposed CY 2017 ASC payment indicator **
369X1 ***	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2 *
36X41 ***	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

*** New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2017. The proposed ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.

b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2016 and Proposed Policy for CY 2017

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. According to that modified ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We then calculate the service (nondevice) portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system. For CY 2015, we implemented a comprehensive APC policy under the OPPS under which we created C–APCs to replace most of the then-current device-dependent APCs and a few nondevice-dependent APCs under the OPPS, which discontinued the device-dependent APC policy (79 FR 66798 through 66810). We did not implement C–APCs in the ASC payment system.

Therefore, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66925), we provided that all separately paid covered ancillary services that are provided integral to covered surgical procedures that mapped to C–APCs continue to be separately paid under the ASC payment system instead of being packaged into the payment for the C–APC as under the OPPS. To avoid duplicating payment, we provided that the CY 2015 ASC payment rates for these C–APCs were based on the CY 2015 OPPS relative payments weights that had been calculated using the standard APC ratesetting methodology for the primary service instead of the relative payment weights that were based on the comprehensive bundled service. For the same reason, under the ASC payment system, we also used the standard OPPS APC ratesetting methodology instead of the C–APC methodology to calculate the device offset percentage for C–APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to C–APCs. Because we implemented the C–APC policy and, therefore, eliminated device-dependent APCs under the OPPS in CY 2015, we revised our definition of ASC device-intensive procedures to be those procedures that are assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology.

We also provided that we would update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our modified definition of device-intensive procedures, reflecting the APC assignments of procedures and APC device offset percentages based on the CY 2013 OPPS claims and cost report data available for the CY 2015 OPPS/ASC proposed rule and final rule with comment period.

(2) Proposed ASC Device-Intensive Designation by HCPCS Code

In CY 2016, we restructured many of the APCs under the OPPS, which resulted in some procedures with significant device costs not being designated device-intensive. In the CY 2016 OPPS/ASC proposed rule (80 FR 39310), we specifically recognized that, in some instances, there may be a surgical procedure that uses a high-cost device but is not assigned to a device-intensive APC. When an ASC covered surgical procedure is not designated as device-intensive, it will be paid under the ASC methodology established for that covered surgical procedure, through either an MPFS nonfacility PE RVU based amount or an OPPS relative payment weight based methodology, depending on the ASC payment indicator assignment.

In response to stakeholder concerns regarding circumstances where procedures with high-cost devices are not classified as device-intensive under the ASC payment system, we solicited public comments in the CY 2016 OPPS/ASC proposed rule, specifically requesting suggestions for alternative methodologies for establishing device-intensive status for ASC covered surgical services (80 FR 39310). We received several comments, which we summarized in the CY 2016 OPPS/ASC final rule with comment period, and we indicated we would take them into consideration for future rulemaking (80 FR 70484). Among the comments we received, several commenters requested that we calculate device intensity at the HCPCS level because the commenters believed the current method of calculating device intensity at the APC level does not take into account device similarity within an APC.

We believe it is no longer appropriate to designate ASC device-intensive procedures based on APC assignment because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. This means that there are some surgical procedures that include high-cost implantable devices that are assigned to an APC with procedures that include the cost of significantly lower-cost devices or no device at all. As a result, the proportion of the APC geometric mean unit cost attributed to implantation of a high-cost device can be underrepresented due to higher claim volume and the lower costs of relatively low-cost device implantation procedures or procedures that do not use an implantable device.

We believe a HCPCS code-level device offset would be a better representation of a procedure's device cost than an APC-wide average device offset based on the device offset of many procedures. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that such a methodological change would result in a more accurate representation of the cost attributable to implantation of a high-cost device, which would ensure consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset would remove inappropriate device-intensive status to procedures without a significant device cost but which are granted such status because of APC assignment.

Therefore, for CY 2017, we are proposing that a procedure with a HCPCS code-level device offset of greater than 40 percent of the APC costs when calculated according to the standard OPPS APC ratesetting methodology would be designated as ASC device-intensive and would be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under our established methodology, including our policies on device credits and discontinued procedures. We are proposing to revise the regulations at 42 CFR 416.171(b)(2) to redefine device-intensive procedures in accordance with this proposal.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, we are proposing to apply device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent would not be calculated from claims data; instead it would be applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41 percent default device offset to new codes that describe procedures that implant medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer. Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status would be applied to the code if the HCPCS code device offset is greater than 40 percent, according to our proposed policy of determining device-intensive status by calculating the HCPCS code-level device offset. The full listing of ASC device-intensive procedures can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

(3) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2017

For CY 2017, we are proposing to revise our methodology for designating ASC covered surgical procedures as device-intensive. Specifically, for CY 2017, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed revised definition of device-intensive procedures, reflecting the proposed individual HCPCS code device offset percentages based on CY 2015 OPPS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures we are proposing to designate as device-intensive and would be subject to the device-intensive procedure payment methodology for CY 2017 can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site). The CPT code, the CPT code short descriptor, the proposed CY 2017 ASC payment indicator, the proposed CY 2017 HCPCS code device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply can also be found in Addendum AA. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on the proposed list of ASC device-intensive procedures.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing

OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

We are proposing to update the list of ASC covered device-intensive procedures, based on the proposed CY 2017 device-intensive definition, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2017. Specifically, when a device-intensive procedure is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS "FB" modifier on the line in the claim with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS "FC" modifier to the HCPCS code for a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures.

We are inviting public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we are proposing to update the list of ASC covered surgical procedures by adding eight procedures to the list for CY 2017. We determined that these eight procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These codes are add-on codes to procedures that are currently performed in the ASC and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we are proposing to include them on the list of ASC covered surgical procedures for CY 2017.

The eight procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2017 payment indicators, are displayed in Table 29 below.

TABLE 29—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2017 ASC payment indicator
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision (List separately in addition to code for primary procedure).	N1
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure).	N1
20938	Autograft for spine surgery only (includes harvesting the graft); structural, biocortical or tricortical (through separate skin fascial incision).	N1

TABLE 29—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017—Continued

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2017 ASC payment indicator
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical C2, each additional interspace (List separately in addition to code for separate procedure).	N1
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22842	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation).	N1
22845	Anterior instrumentation; 2 to 3 vertebral segments	N1
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure).	N1

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include, in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. After reviewing the procedures proposed to be removed from the OPPS IPO list for CY 2017, we also are proposing to add CPT codes 22840, 22842, and 22845 listed in Table 29 above to the ASC list of covered surgical procedures for CY 2017. We are proposing to add these three procedure codes to the ASC list of covered surgical procedures (as well as proposing to remove them from the IPO list) for CY 2017 because these codes are add-on codes to procedures that are currently performed in the ASC and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, we expect that the procedures described by these codes can be safely performed in an ASC without the need for an overnight stay.

Regarding the other codes that we are proposing to remove from the OPPS IPO list, we believe that CPT codes 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure), 31584 (Laryngoplasty; with open reduction of fracture), and 31587 (Laryngoplasty, cricoid split), which also are proposed to be removed from the OPPS IPO list for CY 2017, should continue to be excluded from the ASC list of covered surgical procedures because the procedures described by these codes would generally be expected to require at least an overnight stay.

2. Covered Ancillary Services

a. Proposed List of Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2017 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2017. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2015 may be proposed for packaged status under the CY 2017 OPPS and, therefore, also under the ASC payment system for CY 2017.

To maintain consistency with the OPPS, we are proposing that these services also would be packaged under the ASC payment system for CY 2017. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator "CH," discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2017.

All ASC covered ancillary services and their proposed payment indicators for CY 2017 are included in Addendum BB to this proposed rule. We are inviting public comments on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators "G2" and "A2." Payment indicator "A2" was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator "A2" because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70474 through 70502), we updated the CY 2015 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2," "G2," and "J8" using CY 2014 data, consistent with the CY 2016 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2016 OPPS device offset percentages calculated under the standard APC ratesetting methodology as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2017 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2016 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators "P2," "P3," and "R2") using the most recent available MPFS and OPPS data. We compared the estimated CY 2016 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2016 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator "Q2"), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CYs 2014, 2015, and 2016.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2017

We are proposing to update ASC payment rates for CY 2017 and subsequent years using the established rate calculation methodologies under § 416.171 and using our proposed modified definition of device-intensive procedures, as discussed in section XI.C.1.b. of this proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2017 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2."

We are proposing that payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") be calculated according to our established policies and, for device-intensive procedures, using our proposed modified definition of device-intensive procedures, as discussed in section XI.C.1.b. of this proposed rule. Therefore, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2017 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2017 MPFS nonfacility PE RVU-based amount or the proposed CY 2017 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014, 2015, and 2016, for CY 2017, we are proposing to continue our policy for device removal procedures such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

We are inviting public comments on these proposals.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor "N1") under the ASC payment system (except for device removal codes as discussed in section IV. of this proposed rule). Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to

"Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower.

Similarly, we also finalized our policy to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to the final policies for the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a "device offset" to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator "Z2" and revised the definition of payment indicator "Z2" to include reference to diagnostic services and those for which the payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator "Z3," and revised the definition of payment indicator "Z3" to include reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2017

For CY 2017 and subsequent years, we are proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2017 OPPS and ASC payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2017 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2017 and subsequent year payment rates.

Consistent with established ASC payment policy (72 FR 42497), we are proposing that the CY 2017 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2017 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2017 MPFS proposed rule) and the proposed CY 2017 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). For CY 2017 and subsequent years, we are proposing that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology; or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator "N1"). Radiology services that we are proposing to pay based on the ASC standard ratesetting methodology in CY 2017 and subsequent years are assigned payment indicator "Z2" (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount are assigned payment indicator "Z3" (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We are proposing to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, are proposing to assign payment indicator "Z2" to nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to "Z2" so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology for CY 2017 and subsequent years and, therefore, are proposing to assign the payment indicator "Z2" to radiology services that use contrast agents.

As finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70471 through 70473), we are proposing to continue in CY 2017 to not make separate payment as a covered ancillary service for procurement of corneal tissue when used in any noncorneal transplant procedure under the ASC payment system. We also are proposing for CY 2017 ASC payments to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant.

Consistent with our established ASC payment policy, we are proposing that the CY 2017 payment for devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and would be contractor-priced. Currently, the four devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system); HCPCS code C2613 (Lung biopsy plug with delivery system); HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); and HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components). Consistent with our current policy, we are proposing for CY 2017 that payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight, if the APC weight for the procedure includes similar packaged device costs.

Consistent with our current policy, we are proposing that certain diagnostic tests within the medicine range of CPT codes (that is, all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT) for which separate payment is allowed under the OPPS are covered ancillary services when they are provided integral to an ASC covered surgical procedure. We would pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). There are no additional codes that meet this criterion for CY 2017.

In summary, for CY 2017, we are proposing to continue the methodologies for paying for covered ancillary services established for CY 2016. Most covered ancillary services and their proposed payment indicators for CY 2017 are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled "Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class" posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2017

We did not receive any requests for review to establish a new NTIOL class for CY 2017 by March 1, 2016, the due date published in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2017.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NP" also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator "NP" in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period.

The "CH" comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The "CH" comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

For CY 2017 and subsequent years, we are proposing to continue using the current comment indicators of "NP" and "CH." For CY 2017, there are new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, we are proposing that Category I and III CPT codes that are new and revised for CY 2017 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2017 compared to the CY 2016 descriptors that are included in ASC Addenda AA and BB to this CY 2017 OPPS/ASC proposed rule would be labeled with proposed new comment indicator "NP" to indicate that these CPT and Level II HCPCS codes are open for comment as part of this CY 2017 OPPS/ASC proposed rule. Proposed new comment indicator "NP" means a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year; comments will be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2017 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2017 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term "expenditures" in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2017.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, "[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas." A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_default.*

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS and ASC wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), we proposed to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to use these new definitions to calculate area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. We believe that it is important for the ASC payment system to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, for purposes of the ASC payment system, we are proposing to implement these revisions to the OMB statistical area delineations effective January 1, 2017, beginning with the CY 2017 ASC wage indexes. We are inviting public comments on these proposals.

For CY 2017, the proposed CY 2017 ASC wage indexes fully reflect the new OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin No. 15–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where "contiguous" is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2017 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the

ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2017 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2015, we are proposing to compare the total payment using the CY 2016 ASC relative payment weights with the total payment using the CY 2017 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2016 and CY 2017. We are proposing to use the ratio of CY 2016 to CY 2017 total payment (the weight scalar) to scale the ASC relative payment weights for CY 2017. The proposed CY 2017 ASC scalar is 0.9030 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we have available 98 percent of CY 2015 ASC claims data.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2015 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2015 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for this proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2017, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2015 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2017 ASC wage indexes. Specifically, holding CY 2015 ASC utilization and service-mix and the proposed CY 2017 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2016 ASC wage indexes (which reflect the new OMB delineations and include any applicable transition period) and the total adjusted payment using the proposed CY 2017 ASC wage indexes (which would fully reflect the new OMB delineations). We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2016 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2017 ASC wage indexes and applied the resulting ratio of 0.9992 (the proposed CY 2017 ASC wage index budget neutrality adjustment) to the CY 2016 ASC conversion factor to calculate the proposed CY 2017 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, the statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the

2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the "percentage increase" in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, based on IHS Global Insight's (IGI's) 2016 first quarter forecast with historical data through the fourth quarter of 2015, for the 12-month period ending with the midpoint of CY 2017, the CPI–U update is projected to be 1.7 percent. Also, based on IGI's 2016 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2017 is projected to be 0.5 percent. We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501).

As we discussed in the CY 2011 MPFS final rule with comment period, section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that any annual update to the ASC payment system after application of the quality adjustment be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at: *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of MFP. As we discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501), beginning with the CY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* As discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501), if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For CY 2017, we are proposing to reduce the CPI–U update of 1.7 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.2 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 1.2 percent MFP-adjusted CPI–U update factor to the CY 2016 ASC conversion factor for ASCs meeting the quality reporting requirements. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements. We are proposing to reduce the CPI–U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.5 percentage point MFP reduction. Therefore, we are proposing to apply a −0.8 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2016 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2017 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2017 ASC update for the final rule with comment period.

For CY 2017, we are proposing to adjust the CY 2016 ASC conversion factor ($44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the MFP-adjusted CPI–U update factor of 1.2 percent discussed above, which results in a proposed CY 2017 ASC conversion factor of $44.684 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2016 ASC conversion factor ($44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the quality reporting/MFP-adjusted CPI–U update factor of −0.8 percent discussed above, which results in a proposed CY 2017 ASC conversion factor of $43.801.

We are inviting public comments on these proposals.

3. Display of Proposed CY 2017 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2017 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2017. For a discussion of the MPFS rates, we refer readers to the CY 2017 MPFS proposed rule.

The proposed payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2017 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "Proposed to be Subject to Multiple Procedure Discounting" indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator "CH" in the column titled "Comment Indicator" indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2017. Display of the comment indicator "NI" in the column titled "Comment Indicator" indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator "NP" in the column titled "Comment Indicator" indicates that the code is new (or substantially revised) and that comments will be accepted on the proposed ASC payment indicator assignments for the new code.

The values displayed in the column titled "Proposed CY 2017 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2017. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2017 payment rate displayed in the "Proposed CY 2017 Payment Rate" column, each ASC payment weight in the "Proposed CY 2017 Payment Weight" column was multiplied by the proposed CY 2017 conversion factor of $44.684. The proposed conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the "Proposed CY 2017 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Proposed CY 2017 Payment" column displays the proposed CY 2017 national unadjusted ASC payment rates for all items and services. The proposed CY 2017 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2016.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2017. We are inviting public comment on these proposals.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. In pursuit of these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program has generally been modeled after the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program).

In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for care furnished by:

- Physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP);
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program (HQRP).

In addition, CMS has implemented several value-based purchasing programs, including the Hospital Value-Based Purchasing (VBP) Program and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP), that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and the CMS Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information as part of care delivery.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to our measure selection policy.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from the previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). Quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that rule for more information. We are not proposing any changes to our retention policy for previously adopted measures.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863), for the Hospital IQR Program, we finalized a process for immediate retirement, which we later termed "removal," of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term "retirement" to "removal" in the Hospital OQR Program. We are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of criteria for determining whether to remove measures from the Hospital OQR Program. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our policy on removal of quality measures from the Hospital OQR Program. The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific criterion. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for our list of factors considered in removing measures from the Hospital OQR Program.

We are not proposing any changes to our measure removal policy.

b. Criteria for Removal of "Topped-Out" Measures

We refer readers to CY 2015 OPPS/ASC final rule with comment period where we finalized our proposal to refine the criteria for determining when a measure is "topped-out" (79 FR 66942). We are not proposing any changes to our "topped-out" criteria policy.

4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516) for the previously finalized measure set for the Hospital OQR Program CY 2019 payment determination and subsequent years. These measures also are listed below.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP–1: Median Time to Fibrinolysis.†
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.†
0289	OP–5: Median Time to ECG.†
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
0491	OP–17: Tracking Clinical Results between Visits.†
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
0499	OP–22: ED—Left Without Being Seen.†
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.**
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.**
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
1822	OP–33: External Beam Radiotherapy for Bone Metastases.

† We note that NQF endorsement for this measure was removed.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

5. Proposed New Hospital OQR Program Quality Measures for the CY 2020 Payment Determinations and Subsequent Years

In this proposed rule, for the CY 2020 payment determination and subsequent years, we are proposing a total of seven new measures—two of which are claims-based measures and five of which are Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The claims-based measures are: (1) OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and (2) OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). The OAS CAHPS Survey-based measures are: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility. We discuss these measures in detail below.

a. OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

(1) Background

Cancer care is a priority area for outcome measurement, because cancer is an increasingly prevalent condition associated with considerable morbidity and mortality. In 2015, there were more than 1.6 million new cases of cancer in the United States.[5] Each year, about 22 percent of cancer patients receive chemotherapy,[6] with Medicare payments for cancer treatment totaling $34.4 billion in 2011, almost 10 percent of Medicare fee-for-service (FFS) dollars.[7] With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,[8] a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) The large burden and delayed onset of chemotherapy side effects that patients must manage at home; (2) patients' assumption that little can be done about their symptoms, which leads to them to not seek medical assistance; and (3) limited access to providers who can tailor care to the individual.[9] As a result, cancer patients who receive chemotherapy in a hospital outpatient department require more frequent acute care in the hospital setting and experience more adverse events than cancer patients who are not receiving chemotherapy.[10] [11] [12]

Hospital admissions and ED visits among cancer patients receiving chemotherapy often are caused by predictable, and manageable, side effects from treatment. Recent studies of patients receiving chemotherapy in the outpatient setting show the most commonly cited symptoms and reasons for hospital visits are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.[13] These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. Hospitals that provide outpatient chemotherapy should proactively implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, the National Comprehensive Cancer Network, the Oncology Nursing Society, the Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy.[14] Appropriate outpatient care should curb potentially avoidable hospital admissions and ED visits for these issues and improve cancer patients' quality of life. We believe that including a measure monitoring admissions and ED visits for patients that receive outpatient chemotherapy in the Hospital OQR Program and publicly reporting results would encourage providers to improve their quality of care and lower rates of adverse events that lead to hospital admissions or ED visits after outpatient chemotherapy.

---

[5] American Cancer Society. "Cancer Facts & Figures 2015." Available at: *http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf.*

[6] Klodziej, M., J.R. Hoverman, J.S. Garey, J. Espirito, S. Sheth, A. Ginsburg, M.A. Neubauer, D. Patt, B. Brooks, C. White, M. Sitarik, R. Anderson, and R. Beveridgel. "Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population." *Journal of Oncology Practice,* Vol. 7, 2011, pp. 301–306.

[7] Sockdale, H., K. Guillory. "Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage." Available at: *http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf.*

[8] Vandervelde, Aaron, Henry Miller, and JoAnna Younts. "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration." Washington, DC: Berkeley Research Group, June 2014. Available at: *http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf.* Accessed September 16, 2015.

[9] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

[10] Sadik, M., K. Ozlem, M. Huseyin, B. AliAyberk, S. Ahmet, and O. Ozgur. "Attributes of Cancer Patients Admitted to the Emergency Department in One Year." *World Journal of Emergency Medicine,* Vol. 5, No. 2, 2014, pp. 85–90. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4.*

[11] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[12] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer,* Vol. 22, No. 9, 2014, pp. 2527–2533.

[13] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[14] Several evidence-based guidelines and interventions exist across professional societies. Here we provide three example citations: (1) National Comprehensive Cancer Network. "NCCN Clinical Practice Guidelines in Oncology Version 2.2016. Cancer- and Chemotherapy-Induced Anemia." Fort Washington, PA: NCCN, 2015; (2) Oncology Nursing Society. "Evidence-Based Interventions to Prevent, Manage, and Treat Chemotherapy-Induced Nausea and Vomiting." Available at *http://www.ons.org/Research/PEP/Nausea;* (3) Freifeld, A.G., E.J. Bow, K.A. Sepkowitz, M.J. Boeckh, J.I. Ito, C.A. Mullen, I.I. Raad, K.V. Rolston, J.H. Young, and J.R. Wingard. "Clinical Practice Guideline for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer: 2010 Update by the Infections Diseases Society of America." *Clinical Infectious Diseases,* vol. 52, no. 4: 2011, pp. e56–e93.

(2) Overview of Measure

We believe it is important to reduce adverse patient outcomes associated with chemotherapy treatment in the hospital outpatient setting. Therefore, we are proposing to adopt OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy in the Hospital OQR Program for the CY 2020 payment determination and subsequent years. This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in a hospital outpatient setting. Improved hospital management of these potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—can reduce admissions and ED visits for these conditions. Measuring potentially avoidable admissions and ED visits for cancer patients receiving outpatient chemotherapy will provide hospitals with an incentive to improve the quality of care for these patients by taking steps to prevent and better manage side effects and complications from treatment.

In addition, this measure addresses the National Quality Strategy priority of "promoting the most effective prevention and treatment practices" for the leading causes of mortality. We expect the measure would promote improvement in patient care over time because measuring this area, coupled with transparency in publicly reporting scores, will make potentially preventable hospital inpatient admissions and ED visits following chemotherapy more visible to providers and patients and will encourage providers to incorporate quality improvement activities in order to reduce these visits. This risk-standardized quality measure will address an existing information gap and promote quality improvement by providing feedback to hospitals and physicians, as well as transparency for patients on the rates and variation across hospitals in these potentially preventable admissions and ED visits following chemotherapy.

The measure is well-defined, precisely specified, and allows for valid comparisons of quality among hospitals. The measure includes only outcome conditions demonstrated in the literature as being potentially preventable in this patient population, is important to patients, is specified to attribute an outcome to other hospital(s) that provided outpatient chemotherapy in the 30 days preceding the outcome, and is risk-adjusted for patient demographics, cancer type, clinical comorbidities, and treatment exposure. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and adequately identify differences in quality. We conducted additional assessments to determine the impact of including sociodemographic status (SDS) factors in the risk-adjustment model, and NQF will review our methodology and findings under the NQF trial period described below.

Section 1890A(a)(2) of the Act outlines the prerulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public, by December 1 of each year, a list of quality and efficiency measures that the Secretary is considering. This measure (MUC ID: 15–951) was included on a publicly available document titled "List of Measures under Consideration for December 1, 2015" on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2015-Measures-Under-Consideration-List.pdf* in compliance with section 1890A(a)(2) of the Act.

The Measure Applications Partnership (MAP), which represents stakeholder groups, conditionally supported the measure recommending that it be submitted for National Quality Forum (NQF) endorsement with a special consideration for SDS adjustments and the selection of exclusions. MAP members noted the potential for the measure to increase care coordination and spur patient activation. We refer readers to the Spreadsheet of MAP 2016 Final Recommendations available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of SDS on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for SDS factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of SDS factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of SDS factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without SDS factors in the risk-adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

In addition, several MAP members noted the alignment of this measure concept with other national priorities, such as improving patient experience, and other national initiatives to improve cancer care, as well as the importance of this measure to raise awareness and create a feedback loop for providers (meeting transcript available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81391*). As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings that reflect consensus among affected parties, and to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(17)(C)(i) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity, or by the NQF specifically. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment.

We believe that this proposed measure reflects consensus among the affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the program. Further, the measure was subject to public input during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (MUC ID: 15–951; Spreadsheet of MAP 2016 Final Recommendations available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*). We also note that we submitted this measure to NQF as part of the NQF Cancer Consensus Development Project in March 2016, and it is currently undergoing review.

Currently, there are no publicly available quality of care reports for providers or hospitals that provide outpatient chemotherapy treatment. Thus, adoption of this measure would provide an opportunity to enhance the information available to patients choosing among providers who offer outpatient chemotherapy. We believe this measure would reduce adverse patient outcomes after outpatient chemotherapy by capturing and making more visible to providers and patients hospital admissions and emergency department visits for symptoms that are potentially preventable through high quality outpatient care. Further, providing outcome rates to providers will make visible to clinicians, meaningful quality differences and encourage improvement.

(3) Data Sources

The proposed OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a claims-based measure. It uses Medicare Part A and Part B administrative claims data from Medicare FFS beneficiaries receiving chemotherapy treatment in a hospital outpatient setting. The performance period for the measure is 1 year (that is, the measure calculation includes eligible patients receiving outpatient chemotherapy during a 1-year timeframe). For example, for the CY 2020 payment determination, the performance period would be CY 2018 (that is, January 1, 2018 through December 31, 2018).

(4) Measure Calculation

The OP–35 measure involves calculating two mutually exclusive outcomes: (1) One or more inpatient admissions; or (2) one or more ED visits for any of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment among cancer patients receiving treatment in a hospital outpatient setting. These 10 conditions are potentially preventable through appropriately managed outpatient care. Therefore, two scores will be reported for this measure. A patient can only be counted for any measured outcome once, and those who experience both an inpatient admission and an ED visit during the performance period are counted towards the inpatient admission outcome. These two distinct rates provide complementary and comprehensive performance estimates of quality of care following hospital-based outpatient chemotherapy treatment. We calculate the rates separately, because the severity and cost of an inpatient admission is different from that of an ED visit, but both adverse events are important signals of quality and represent patient-important outcomes of care.

The measure derives and reports the two separate scores, one for each mutually exclusive outcome, (also referred to as the hospital-level risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR)), each calculated as the ratio of the number of "predicted" to the number of "expected" outcomes (inpatient admissions or ED visits, respectively), multiplied by the national observed rate (of inpatient admissions or ED visits). For the RSAR and RSEDR, the numerator of the ratio is the number of patients predicted to have the measured adverse outcome (an inpatient admission for RSAR or ED visit for RSEDR with one or more of the 10 diagnoses described above within 30 days) based on the hospital's performance with its observed case-mix. The denominator for each ratio is the number of patients expected to have the measured adverse outcome based on the average national performance and the hospital's observed case-mix. The national observed rate is the national unadjusted number of patients who have the adverse outcome among all qualifying patients who had at least one chemotherapy treatment in a hospital.

We define the window for identifying the outcomes of admissions and ED visits as 30 days after hospital outpatient chemotherapy treatment, as existing literature suggests the vast majority of adverse events occur within that timeframe.[15] [16] [17] Limiting the window to 30 days after each outpatient chemotherapy treatment also: (1) Helps link patients' experiences to the hospitals that provided their recent treatment, while accounting for variations in duration between outpatient treatments; (2) supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the disease or other unrelated events; and (3) is a clinically reasonable timeframe to observe related side effects. For additional details on how the measure is calculated, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(5) Cohort

The cohort includes Medicare FFS patients ages 18 years and older as of the start of the performance period with a diagnosis of any cancer (except leukemia) who received at least one hospital outpatient chemotherapy treatment at a reporting hospital during the performance period. Based on discussions with clinical and technical panel experts, the measure excludes cancer patients with a diagnosis of leukemia at any time during the performance period due to the high toxicity of treatment and recurrence of disease. Therefore, admissions for leukemia patients may not reflect poorly managed outpatient care, but rather disease progression and relapse. The measure also excludes patients who were not enrolled in Medicare FFS Parts A and B in the year before the first outpatient chemotherapy treatment during the performance period, because the risk-adjustment model (explained further below) uses claims data for the year before the first chemotherapy treatment during the performance period to identify comorbidities. Lastly, the measure excludes patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure, to ensure all patients have complete data available for outcome assessment.

---

[15] Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." Supportive Care in Cancer, Vol. 21, No. 2, 2013, pp. 397–404.

[16] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." Supportive Care in Cancer, Vol. 22, No. 9, 2014, pp. 2527–2533.

[17] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." Supportive Care in Cancer, Vol. 19, No. 7, 2011, pp. 963–969.

(6) Risk Adjustment

Since the measure has two mutually exclusive outcomes (qualifying inpatient admissions and qualifying ED visits), we developed two risk-adjustment models. The only differences between the two models are the clinically relevant demographic, comorbidity, and cancer type variables used for risk adjustment. The statistical risk-adjustment model for inpatient admissions includes 20 demographic and clinically relevant risk-adjustment variables that are strongly associated with risk of one or more hospital admissions within 30 days following chemotherapy in a hospital outpatient setting. On the other hand, the statistical risk-adjustment model for ED visits include 15 demographic and clinically relevant risk-adjustment variables that are strongly associated with risk of one or more ED visits within 30 days following chemotherapy in a hospital outpatient setting. For additional methodology details, including the complete list of risk-adjustment variables, we refer readers to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We are inviting public comments on our proposal to adopt the OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure to the Hospital OQR Program for the CY 2020 payment determination and subsequent years as discussed above.

b. OP–36: Hospital Visits After Hospital Outpatient Surgery Measure (NQF #2687)

(1) Background

Outpatient same-day surgery is common in the United States. Nearly 70 percent of all surgeries in the United States are now performed in the outpatient setting, with most performed as same-day surgeries at hospitals.[18] Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times, avoidance of hospitalizations, and rapid return home.[19] Furthermore, same-day surgery costs significantly less than an equivalent inpatient surgery, and therefore, presents a significant cost saving opportunity to the health system.[20] With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unanticipated hospital visits. Similarly, direct admissions after surgery that are primarily caused by nonclinical patient considerations (such as lack of transport home upon discharge) or facility logistical issues (such as delayed start of surgery) are common causes of unanticipated yet preventable hospital admissions following same-day surgery. Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. National estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery.[21] [22] [23] [24] [25] [26] [27] [28] Furthermore, hospital visit rates vary among hospitals,[29] suggesting variation in surgical and discharge care quality. However, providers (hospitals and surgeons) are often unaware of their patients' hospital visits after surgery because patients often present to the ED or to different hospitals.[30] This risk-standardized measure would provide the opportunity for providers to improve the quality of care and to lower the rate of preventable adverse events that occur after outpatient surgery.

(2) Overview of Measure

We believe it is important to reduce adverse patient outcomes associated with preparation for surgery, the procedure itself, and follow-up care. Therefore, we are proposing to include OP–36: Hospital Visits after Hospital Outpatient Surgery in the Hospital OQR Program for the CY 2020 payment determination and subsequent years.

We expect that the measure would promote improvement in patient care over time because measuring this area, coupled with transparency in publicly reporting scores, will make patient unplanned hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients and encourage providers to engage in quality improvement activities in order to reduce these visits. This measure meets the National Quality Strategy priority of "promoting effective communication and coordination of care." Many providers are unaware of the post-surgical hospital visits that occur because patients often present to the ED or to different hospitals. Reporting this outcome will illuminate problems that may not currently be visible. In addition, the outcome of unplanned hospital visits is a broad, patient-centered outcome that reflects the full range of reasons leading to hospitalization among patients undergoing same-day surgery. This risk-standardized quality measure would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after outpatient same-day surgery.

---

[18] Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. National health statistics reports. Jan 28 2009(11):1–25.

[19] International Association for Ambulatory Surgery. Day Surgery: Development and Practice. International Association for Ambulatory Surgery (IASS); 2006. Available at: *http://www.iaas-med.com/files/historical/DaySurgery.pdf.*

[20] Majholm B, Engbaek J, Bartholdy J, et al. Is day surgery safe? A Danish multicentre study of morbidity after 57,709 day surgery procedures. Acta anaesthesiologica Scandinavica. Mar 2012; 56(3):323–331.

[21] Ibid.

[22] Linares-Gil MJ, Pelegri-Isanta MD, Pi-Siqués F, Amat-Rafols S, Esteva-Ollé MT, Gomar C. Unanticipated admissions following ambulatory surgery. *Ambulatory Surgery.* 1997; 5(4):183–188.

[23] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. Archives of surgery (Chicago, Ill.: 1960). Jan 2004;139(1):67–72.

[24] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of Clinical Anesthesia.* Aug 2002; 14(5):349–353.

[25] Hollingsworth JM, Saigal CS, Lai JC, Dunn RL, Strope SA, Hollenbeck BK. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *The Journal of Urology.* Oct 2012; 188(4):1274–1278.

[26] Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: patient satisfaction and outcomes. Quality in health care: QHC. Jun 1999; 8(2):86–91.

[27] Fortier J, Chung F, Su J. Unanticipated admission after ambulatory surgery—a prospective study. Canadian journal of anaesthesia = *Journal Canadien d'Anesthesie.* Jul 1998; 45(7):612–619.

[28] Aldwinckle RJ, Montgomery JE. Unplanned admission rates and postdischarge complications in patients over the age of 70 following day case surgery. *Anaesthesia.* Jan 2004; 59(1):57–59.

[29] Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: Patient satisfaction and outcomes. Quality in health care: QHC. Jun 1999; 8(2):86–91.

[30] Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. Annals of surgery. Nov 1999; 230(5):721–727.

Currently, there are no publicly available quality of care reports for providers or facilities that conduct same-day surgery in the hospital outpatient setting. Thus, this measure addresses an important quality measurement gap, and there is an opportunity to enhance the information available to patients choosing among hospitals that provide same-day outpatient surgery. Furthermore, providing outcome rates to hospitals will make visible to clinicians, meaningful quality differences and incentivize improvement.

This measure (MUC ID: 15–982) was included on a publicly available document titled "MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals" on the NQF Web site at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688* (formerly referred to as the "list of Measures Under Consideration") in compliance with section 1890A(a)(2) of the Act.

The measure received NQF endorsement on September 3, 2015.[31] In addition, the MAP supported the measure for program use citing the vital importance of measures that help facilities reduce unnecessary hospital visits.[32] Some members cautioned that because the measure was endorsed by NQF before the start of the SDS trial period, the measure should be reexamined during maintenance to determine whether SDS adjustments are needed.[33]

We believe that this proposed measure reflects consensus among the affected parties because the measure was subject to public comment during the MAP and measure development processes, with public commenters agreeing with the MAP's conclusions on the measure.[34] As stated above, this measure also was endorsed by the NQF.

We understand the important role that sDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of SDS on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

(3) Data Sources

The proposed OP–36: Hospital Visits after Hospital Outpatient Surgery measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries with outpatient same-day surgery. The performance period for the measure is 1 year (that is, the measure calculation includes eligible outpatient same-day surgeries occurring within a one-year timeframe). For example, for the FY 2020 payment determination, the performance period would be CY 2018 (that is, January 1, 2018 through December 31, 2018).

(4) Measure Calculation

The measure outcome is any of the following hospital visits: (1) An inpatient admission directly after the surgery; or (2) an unplanned hospital visit (ED visits, observation stays, or unplanned inpatient admissions) occurring after discharge and within 7 days of the surgery. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The facility-level measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital's patients. The numerator of the ratio is the number of hospital visits predicted for the hospital's patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital's case mix and surgical procedure mix. A ratio of less than one indicates the hospital's patients were estimated as having fewer post-surgical visits than expected compared to hospitals with similar surgical procedures and patients; and a ratio of greater than one indicates the hospital's patients were estimated as having more visits than expected.

In order to ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of hospital surgeries potentially affected by the CMS 3-day payment window policy, we identified physician claims for same-day surgeries in the hospital setting from the Medicare Part B Standard Analytical Files (SAF) with an inpatient admission within 3 days and lacking a corresponding hospital facility claim. We then attribute the surgery identified as affected by this policy to the appropriate hospital facility using the facility provider identification from the inpatient claim.

For additional methodology details, we refer readers to the documents posted at: *http://www.cms.gov/Medicare/QualityInitiatives-Patient-AssessmentInstruments/HospitalQualityInits/Measure-Methodology.html* under "Hospital Outpatient Surgery."

(5) Cohort

The measure includes Medicare FFS patients aged 65 years and older undergoing same-day surgery (except eye surgeries) in hospitals.

"Same-day surgeries" are substantive surgeries and procedures listed on Medicare's list of covered ASC procedures. Medicare developed this list to identify surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening.

---

[31] MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2016. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688.*

[32] Spreadsheet of MAP 2016 Final Recommendations. February 1, 2016. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[33] Ibid.

[34] MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2016. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81688.*

Although Medicare developed this list of surgeries for ASCs, we use it for this hospital outpatient measure for two reasons. First, it aligns with our target cohort of surgeries that have a low to moderate risk profile and are safe to be performed as same-day surgeries. By only including surgeries on this list in the measure, we effectively do not include surgeries performed at hospitals that typically require an overnight stay which are more complex, higher risk surgeries. Second, we use this list of surgeries because it is annually reviewed and updated by Medicare, and includes a transparent public comment submission and review process for addition and/or removal of procedures codes. The list for 2016 is posted at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending* (refer to Addendum AA on the CMS Web site).

The measure cohort excludes eye surgeries. Although eye surgery is considered a substantive surgery, its risk profile is more representative of "minor" surgery, in that it is characterized by high volume and a low outcome ratio. The measure cohort also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 7 days after the procedure to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

The statistical risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following outpatient surgery. The measure risk adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the Work Relative Value Units (RVUs).[35] Work RVUs are assigned to each CPT procedure code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification System (CCS),[36] to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We are inviting public comment on our proposal to adopt the OP–36 Hospital Visits after Hospital Outpatient Surgery measure (NQF #2687) to the Hospital OQR Program for the CY 2020 payment determination and subsequent years as discussed above.

c. OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

(1) Background

Currently, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within a hospital outpatient department. Some hospital outpatient departments are conducting their own surveys and reporting these results on their Web sites, but there is not one standardized survey in use to assess patient experiences with care in hospital outpatient departments that would allow valid comparisons across hospital outpatient departments. Patient-centered experience measures are a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.[37] In addition, information on patient experience with care at a provider/facility is an important quality indicator to help providers and facilities improve services furnished to their patients and to assist patients in choosing a provider/facility at which to seek care.

(2) Overview of Measures

The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey was developed as part of the U.S. Department of Health and Human Services' (HHS) Transparency Initiative to measure patient experiences with hospital outpatient care.[38] In 2006, CMS implemented the Hospital CAHPS (HCAHPS) Survey, which collects data from hospital inpatients about their experience with hospital inpatient care (71 FR 48037 through 48039). The HCAHPS Survey, however, is limited to data from patients who receive inpatient care for specific diagnosis-related groups for medical, surgical, and obstetric services; it does not include patients who received outpatient surgical care or procedures from ASCs or hospitals. We note that the OAS CAHPS Survey was developed to assess patients' experience of care following a procedure or surgery in a hospital outpatient department; therefore, the survey does not apply to emergency departments. Throughout the development of the OAS CAHPS Survey, CMS considered the type of data collected for HCAHPS and other existing CAHPS surveys as well as the terminology and question wording to maximize consistency across CAHPS surveys. CMS has developed similar surveys for other settings of care that are currently used in other quality reporting and value-based purchasing programs, such as the Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQRP (80 FR 47141 through 47207).

The OAS CAHPS Survey contains 37 questions that cover topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey also contains two global rating questions and asks for self-reported health status and basic demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The basic demographic information is captured in the OAS CAHPS Survey through standard AHRQ questions used to develop case-mix adjustment models for the survey. Furthermore, the survey development process followed the principles and guidelines outlined by AHRQ and its CAHPS Consortium®. The OAS CAHPS Survey received the registered CAHPS trademark in April 2015. OAS CAHPS Survey questions can be found at *https://oascahps.org/*

---

[35] S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: *http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf.*

[36] HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality, Rockville, MD *http://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp*, 2014.

[37] CMS National Quality Strategy 2016. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[38] U.S. Department of Health and Human Services. *HHS Strategic Plan, Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.* Feb. 2016. Available at: *http://www.hhs.gov/about/strategic-plan/strategic-goal-4/index.html.*

Survey-Materials under "Questionnaire."

We are proposing to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years—three OAS CAHPS composite survey-based measures and two global survey-based measures (discussed below). We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between hospital outpatient departments. We note that we are making similar proposals in the ASCQR Program in section XIV.B.4.c. of this proposed rule. The three OAS CAHPS composite survey-based measures are:

- OP–37a: OAS CAHPS—About Facilities and Staff;
- OP–37b: OAS CAHPS—Communication About Procedure; and
- OP–37c: OAS CAHPS—Preparation for Discharge and Recovery.

Each of the three OAS CAHPS composite survey-based measures consists of six or more questions.

Furthermore, the two global survey-based measures are:

- OP–37d: OAS CAHPS—Overall Rating of Facility; and
- OP–37e: OAS CAHPS—Recommendation of Facility.

The two global survey-based measures are comprised of a single question each and ask the patient to rate the care provided by the hospital and their willingness to recommend the hospital to family and friends. More information about these measures can be found at the OAS CAHPS Survey Web site (*https://oascahps.org*).

The five survey-based measures (MUC IDs: X3697; X3698; X3699; X3702; and X3703) we are proposing were included on the CY 2014 MUC list,[39] and reviewed by the MAP.[40] The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.[41] The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.[42] Further, the MAP stated that given that these measures are also under consideration for the ASCQR Program, they help to promote alignment across care settings.[43] It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient reported outcomes and patient and family engagement.[44] Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities are not overburdened.[45]

These measures have been fully developed since being submitted to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ[46] and its CAHPS Consortium[47] in developing a patient experience of care survey, such as: Reporting on actual patient experiences; standardization across the survey instrument; administration protocol; data analysis and reporting; and extensive testing with consumers. Development also included: Reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; and conducting a field test.

In addition, we received public input from several modes. We published a request for information on January 25, 2013 (78 FR 5460) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. Stakeholder input was also obtained through communications with a Technical Expert Panel (TEP) comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development.

After we determined that the survey instrument was near a final form, we tested the effect of various data collection modes (that is, mail-only, telephone-only, or mail with telephone follow-up of non-respondents) on survey responses. In addition, we began voluntary national implementation of the OAS CAHPS Survey in January 2016.[48]

In addition, while the proposed OAS CAHPS Survey-based measures are not currently NQF-endorsed, they will be submitted to the NQF for endorsement under an applicable call for measures in the near future.

In section XIX. of this proposed rule, the Hospital VBP Program is proposing to remove the HCAHPS Pain Management dimension (which consists of three questions) in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain due to confusion about the intent of these questions and the public health concern about the ongoing prescription opioid overdose epidemic. For more information about the pain management questions captured in the HCAHPS Survey and their use in the Hospital VBP Program, we refer readers to section XIX.B.3. of this proposed rule.

The OAS CAHPS Survey also contains two questions regarding pain management. We believe pain management is an important dimension of quality, but realize that there are concerns about these types of questions. We refer readers to section XIX. of this proposed rule for more information on stakeholders' concerns. However, the pain management questions in the OAS CAHPS Survey are very different from those contained in the HCAHPS Survey because they focus on communication regarding pain management rather than pain control. Specifically, the OAS CAHPS Survey pain management communication questions read:

Q: Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?

☐ A1: Yes, definitely.
☐ A2: Yes, somewhat.
☐ A3: No.

---

[39] National Quality Forum. List of Measures under Consideration for December 1, 2014. National Quality Forum, Dec. 2014. Available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.*

[40] National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] Ibid.

[45] Ibid.

[46] Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys". Available at: *https://cahps.ahrq.gov/about-cahps/principles/index.html.*

[47] Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: *https://cahps.ahrq.gov/about-cahps/cahps-program/index.html.*

[48] Outpatient and Ambulatory Surgery CAHPS Survey: "National Implementation." Available at: *https://oascahps.org/General-Information/National-Implementation.*

Q: At any time after leaving the facility, did you have pain as a result of your procedure?[49]

☐ A1: Yes.
☐ A2: No.

Unlike the HCAHPS pain management questions, which directly address the adequacy of the hospital's pain management efforts, such as prescribing opioids, the OAS CAHPS pain management communication questions focus on the information provided to patients regarding pain management following discharge from a hospital. We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. We also note that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. In addition, we note that, unlike in the Hospital VBP Program, there is no link between scoring well on the questions and higher hospital payments. However, we also recognize that questions remain about the ongoing prescription opioid epidemic. For these reasons, we are proposing to adopt the OAS CAHPS Survey measures as described in this section, including the pain management communication questions, but will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns. We also welcome feedback on these pain management communication questions for use in future revisions of the OAS CAHPS Survey.

(3) Data Sources

As discussed in the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*), the survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to section XIII.D.4. of this proposed rule for an in-depth discussion of the data submission requirements associated with the proposed OAS CAHPS Survey measures. To summarize, to meet the OAS CAHPS Survey requirements for the Hospital OQR Program, we are proposing that hospitals contract with a CMS-approved vendor to collect survey data for eligible patients at the hospitals on a monthly basis and report that data to CMS on the hospital's behalf by the quarterly deadlines established for each data collection period. Hospitals may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions hospitals develop or use from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Q1–Q24). The list of approved vendors is available at: *https://oascahps.org*. We also are proposing to codify the OAS CAHPS Survey administration requirements for hospitals and vendors under the Hospital OQR Program at 42 CFR 419.46(g), and refer readers to section XIII.D.4. of this proposed rule for more details. It should be noted that nondiscrimination requirements for effective communication with persons with disabilities and language access for persons with limited English proficiency should be considered in administration of the surveys. For more information, we refer readers to *http://www.hhs.gov/civil-rights*.

We are proposing that the data collection period for the OAS CAHPS Survey measures would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, hospitals would be required to collect data on a monthly basis, and submit this collected data on a quarterly basis, for January 1, 2018—December 31, 2018 (CY 2018).

We are further proposing that, as discussed in more detail below, hospitals will be required to survey a random sample of eligible patients on a monthly basis. A list of acceptable sampling methods can be found in the OAS CAHPS Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*). We are also proposing that hospitals would be required to collect at least 300 completed surveys over each 12-month reporting period (an average of 25 completed surveys per month). We acknowledge that some smaller hospitals may not be able to collect 300 completed surveys during a 12-month period; therefore, we are proposing an exemption for facilities with lower patient censuses. Hospitals would have the option to submit a request to be exempted from performing the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the year preceding the data collection period. We refer readers to section XIII.B.5.c.(6) for details on this proposal. However, we believe it is important to capture patients' experience of care at hospitals. Therefore, except as discussed in section XIII.B.5.c.(6) of this proposed rule below, we also are proposing that smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period will only be required to collect as many completed surveys as possible, during that same time period, with surveying all eligible patients (that is, no sampling). For more information regarding these survey administration requirements, we refer readers to the OAS CAHPS Survey Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*).

Furthermore, we are proposing that hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level. In other words, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the Medicare participating hospital level as identified by the hospital's CCN. Therefore, the reporting for a CCN would include all eligible patients from all eligible hospital locations of the Medicare participating hospital that is identified by the CCN.

(4) Measure Calculations

As noted above, we are proposing to adopt three composite OAS CAHPS Survey-based measures (OP–37a, OP–37b, and OP–37c) and two global OAS CAHPS Survey-based measures (OP–37d and OP–37e). As with the other measures adopted for the Hospital OQR Program, a hospital's performance for a given payment determination year will be based upon the successful submission of all required data in accordance with the administrative, form, manner and timing requirements established for the Hospital OQR Program. Our proposals for OAS CAHPS data submission requirements are discussed in section XIII.D.4. of this proposed rule. Therefore, hospitals' scores on the OAS CAHPS Survey-based measures, discussed below, will not affect whether they are subject to the 2.0 percentage point payment reduction for hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary. These measure calculations will be used for public reporting purposes only.

(A) Composite Survey-Based Measures

Hospital rates on each composite OAS CAHPS Survey-based measure would be calculated by determining the proportion of "top-box" responses (that is "Yes" or "Yes Definitely") for each question within the composite and averaging these proportions over all questions in the composite measure. For example, to assess hospital performance on the composite measure OP–37a: OAS CAHPS—About Facilities and Staff, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (that is, six).

---

[49] We note that this question is a control question only used to determine if the facility should have given a patient additional guidance on how to handle pain after leaving the facility. The facility is not scored based on this question.

As a specific example, we take a hospital that had 50 surveys completed and received the following proportions of "top-box" responses through sample calculations:

- 25 "top-box" responses out of 50 total responses on Question One
- 40 "top-box" responses out of 50 total responses on Question Two
- 50 "top-box" responses out of 50 total responses on Question Three
- 35 "top-box" responses out of 50 total responses on Question Four
- 45 "top-box" responses out of 50 total responses on Question Five
- 40 "top-box" responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that hospital's measure score for public reporting as follows:

$$\text{Hospital Publicly Reported Score} = \frac{(0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)}{6}$$

This calculation would give this example hospital a raw score of 0.78 or 78 percent for the OP–37a measure for purposes of public reporting. We note that each percentage would then be adjusted for differences in the characteristics of patients across hospitals as described in XIII.B.5.c.(7) of this proposed rule, below. As a result, the final percentages may vary from the raw percentage as calculated in the example above.

(B) Global Survey-Based Measures

We are proposing to adopt two global OAS CAHPS Survey measures. OP–37d asks the patient to rate the care provided by the hospital on a scale of 0 to 10, and OP–37e asks about the patient's willingness to recommend the hospital to family and friends on a scale of "Definitely No" to "Definitely Yes." Hospital performance on each of the two global OAS CAHPS Survey-based measures would be calculated by proportion of respondents providing high-value responses (that is, a 9–10 rating or "Definitely Yes") to the survey questions over the total number of respondents. For example, if a hospital received 45 9- and 10-point ratings out of 50 responses, this hospital would receive a 0.9 or 90 percent raw score, which would then be adjusted for differences in the characteristics of patients across hospitals as described in section XIII.B.5.c.(7) below, for purposes of public reporting.

(5) Cohort

The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. Eligible patients, regardless of insurance or method of payment, can participate.

For purposes of each survey-based measures captured in the OAS CAHPS Survey, an "eligible patient" is a patient 18 years or older:

- Who had an outpatient surgery or procedure in a hospital, as defined in the OAS CAHPS Survey Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*);
- Who does not reside in a nursing home;
- Who was not discharged to hospice care following their surgery;
- Who is not identified as a prisoner; and
- Who did not request that hospitals not release their name and contact information to anyone other than hospital personnel.

There are a few categories of otherwise eligible patients who are excluded from the measure as follows:

- Patients whose address is not a U.S. domestic address;
- Patients who cannot be surveyed because of State regulations;
- Patient's surgery or procedure does not meet the eligibility CPT or G-codes as defined in the OAS CAHPS Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*); and
- Patients who are deceased.

(6) Exemption

We understand that hospitals with lower patient censuses may be disproportionately impacted by the burden associated with administering the survey and the resulting public reporting of OAS CAHPS Survey results. Therefore, we are proposing that hospitals may submit a request to be exempted from participating in the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the "eligibility period," which is the calendar year before the data collection period. All exemption requests will be reviewed and evaluated by CMS. For example, for the CY 2020 payment determination, this exemption request would be based on treating fewer than 60 survey-eligible patients in CY 2017, which is the calendar year before the data collection period (CY 2018) for the CY 2020 payment determination.

To qualify for the exemption, hospitals must submit a participation exemption request form, which will be made available on the OAS CAHPS Survey Web site (*https://oascahps.org*) on or before May 15 of the data collection calendar year. For example, the deadline for submitting an exemption request form for the CY 2020 payment determination would be May 15, 2018. We determined the May 15 deadline in order to align with the deadline for submitting Web-based measures, and because we believe this deadline provides hospitals with sufficient time to review the previous years' patient lists and determine whether they are eligible for an exemption based on patient population size.

In addition, as discussed above, hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level; therefore, an individual hospital that meets the exemption criteria outlined above may submit a participation exemption request form. CMS will then assess that hospital's eligibility for a participation exemption due to facility size. However, no matter the number of hospital locations of the Medicare participating hospital, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the Medicare participating hospital level, as identified by its CCN. Therefore, the reporting for a CCN would include all eligible patients from all locations of the eligible Medicare participating hospital as identified by its CCN.

(7) Risk Adjustment

In order to achieve the goal of fair comparisons across all hospitals, we believe it is necessary and appropriate to adjust for factors that are not directly related to hospital performance, such as patient case-mix, for these OAS CAHPS Survey measures. The survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. These factors influence how patients respond to the survey but are beyond the control of the hospital and are not directly related to hospital performance. For more information about patient-mix adjustment for these measures, we refer readers to *https://oascahps.org/General-Information/Mode-Experiment*.

(8) Public Reporting

We will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the Hospital OQR Program, we are not proposing a format or timing for public reporting of OAS CAHPS Survey data at this time.

As currently proposed, hospital locations that are part of the same Medicare participating hospital (operates under one Medicare provider agreement and one CCN) must combine data for collection and submission for the OAS CAHPS Survey across their multiple facilities. These results from multiple locations of the Medicare participating hospital would then be combined and publicly reported on the Hospital Compare Web site for the single Medicare participating hospital. To increase transparency in public reporting and improve the usefulness of the Hospital Compare Web site, we intend to note on the Web site instances where publicly reported measures combine results from two or more locations of a single multi-location Medicare participating hospital.

We are inviting public comments on our proposals as discussed above to adopt, for the CY 2020 payment determination and subsequent years, the five survey-based measures: (1) OP–37a: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility.

d. Summary of Previously Adopted and Newly Proposed Hospital OQR Program Measures for the CY 2020 Payment Determinations and Subsequent Years

The table below outlines the proposed Hospital OQR Program measure set for the CY 2020 payment determination and subsequent years, and includes both previously adopted measures and measures newly proposed in this proposed rule.

PROPOSED AND PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP–1: Median Time to Fibrinolysis.†
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.†
0289	OP–5: Median Time to ECG.†
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
0491	OP–17: Tracking Clinical Results between Visits.†
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
0499	OP–22: ED—Left Without Being Seen.†
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.**
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.***
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.
N/A	OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.****
2687	OP–36: Hospital Visits after Hospital Outpatient Surgery.****
N/A	OP–37a: OAS CAHPS—About Facilities and Staff.****
N/A	OP–37b: OAS CAHPS—Communication About Procedure.****
N/A	OP–37c: OAS CAHPS—Preparation for Discharge and Recovery.****
N/A	OP–37d: OAS CAHPS—Overall Rating of Facility.****
N/A	OP–37e: OAS CAHPS—Recommendation of Facility.****

† We note that NQF endorsement for this measure was removed.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

**** New measure proposed for the CY 2020 payment determination and subsequent years.

6. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are seeking public comment on future measure topics generally, electronic clinical quality (eCQM) measures implementation, and specifically the future measure concept, Safe Use of Opioids-Concurrent Prescribing eCQM, for future consideration in the Hospital OQR Program. These are discussed in detail below.

a. Future Measure Topics

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of Health Information Technology (health IT), care coordination, patient safety, and volume. Through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, while aligning quality measures across the Medicare program.

We are inviting public comments on possible measure topics for future consideration in the Hospital OQR Program. We are moving towards the use of outcome measures and away from the use of clinical process measures across the Medicare program. We specifically request comment on any outcome measures that would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program

b. Electronic Clinical Quality Measures

We are working toward incorporating electronic clinical quality measures (eCQMs) in the Hospital OQR Program in the future. We believe automated electronic extraction and reporting of clinical quality data, potentially including measure results calculated automatically by appropriately certified health IT, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program. We recognize that considerable work needs to be done by measure stewards and developers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications) for the outpatient setting. This includes completing e-specifications for measures, pilot testing, reliability and validity testing, submitting for endorsement of e-specified version (if applicable) and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems. We continue to work to ensure that eCQMs will be smoothly incorporated into the Hospital OQR Program.

We are inviting public comments on future implementation of eCQMs as well as specific future eCQMs for the Hospital OQR Program.

c. Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing

Unintentional opioid overdose fatalities have become an epidemic in the last 20 years and a major public health concern in the United States.[50] HHS has made addressing opioid misuse, dependence, and overdose a priority. HHS is implementing evidence-based initiatives focused on informing prescribing practices to combat misuse and overdose deaths.[51] Several other organizations, including the Centers for Disease Control and Prevention (CDC), the Federal Interagency Workgroup for Opioid Adverse Drug Events, the National Action Plan for Adverse Drug Event Prevention, and the Substance Abuse and Mental Health Administration, have joined the effort.

Prescribing opioids to patients already using an opioid or patients using benzodiazepines (sedation-inducing central nervous system depressant) increases their risk of respiratory depression and death.[52] These prescribing scenarios can occur in any setting including: Inpatient hospital; outpatient hospital practices; outpatient emergency departments; and other urgent care settings. With a limited evaluation focused on the patient's acute condition, the clinician in these settings may not know the patient's full medical history.[53] An analysis of national prescribing patterns shows that more than half of patients who received an opioid prescription in 2009 had filled another opioid prescription within the previous 30 days.[54] Studies of multiple claims and prescription databases have shown that between 5 and 15 percent of patients receive overlapping opioid prescriptions and 5 to 20 percent of patients receive overlapping opioid and benzodiazepine prescriptions across all settings.[55] [56] [57]

The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain[58] recommends that providers avoid concurrently prescribing opioids and benzodiazepines because rates of fatal overdose are ten times higher in patients who are co-dispensed opioid analgesics and benzodiazepines than opioids alone[59] and concurrent use of benzodiazepines with opioids was prevalent in 31 percent to 51 percent of fatal overdoses.[60] ED visit rates involving both opioid analgesics and benzodiazepines increased from 11.0 in 2004 to 34.2 per 100,000 population in 2011.[61] Opioid overdose events

---

[50] Rudd, R., Aleshire, N., Zibbell, J., et al. "Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014". MMWR, Jan 2016. 64(50);1378–82. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.*

[51] United States Department of Health and Human Services "ASPE Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths". March 2015. Available at: *https://aspe.hhs.gov/sites/default/files/pdf/107956/ib_OpioidInitiative.pdf.*

[52] Dowell, D., Haegerich, T., Chou, R. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016". MMWR Recomm Rep 2016;65. Available at: *http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html.*

[53] Governale, Laura. "Outpatient Prescription Opioid Utilization in the U.S., Years 2000–2009." 2010. Drug Utilization Data Analysis Team Leader, Division of Epidemiology, Office of Surveillance and Epidemiology. Presentation for U.S. Food and Drug Administration. Available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM220950.pdf.*

[54] National Institute on Drug Abuse. "Analysis of opioid prescription practices finds areas of concern". April 2011. Available at: *https://www.drugabuse.gov/news-events/news-releases/2011/04/analysis-opioid-prescription-practices-finds-areas-concern.*

[55] Liu, Y., Logan, J., Paulozzi, L., et al. "Potential Misuse and Inappropriate Prescription Practices Involving Opioid Analgesics". Am J Manag Care. 2013 Aug;19(8):648–65.

[56] Mack, K., Zhang, K., et al. "Prescription Practices involving Opioid Analgesics among Americans with Medicaid, 2010," J Health Care Poor Underserved. 2015 Feb; 26(1): 182–198. Available at: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365785/.*

[57] Jena, A., et al. "Opioid prescribing by multiple providers in Medicare: Retrospective observational study of insurance claims," BMJ 2014; 348:g1393 doi: 10.1136/bmj.g1393. Available at: *http://www.bmj.com/content/348/bmj.g1393.*

[58] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65:1–49. DOI: *http://dx.doi.org/10.15585/mmwr.rr6501e1.*

[59] Dasgupta, N., et al. "Cohort Study of the Impact of High-dose Opioid Analgesics on Overdose Mortality," Pain Medicine, Wiley Periodicals, Inc., 2015.

[60] Dowell, D., Haegerich, T., Chou, R. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016." MMWR Recomm Rep 2016;65. Available at: *http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html.*

[61] Jones, CM., McAninch, JK. "Emergency Department Visits and Overdose Deaths From Combined Use of Opioids and Benzodiazepines". Am J Prev Med. 2015 Oct;49(4):493–501. doi: 10.1016/j.amepre.2015.03.040. Epub 2015 Jul 3.

Continued

resulting in ED use can cost the United States approximately $800 million per year.[62]

To address concerns associated with overlapping or concurrent prescribing of opioids or opioids and benzodiazepines, we are in early development of a new electronic clinical quality measure for the Hospital IQR and OQR Programs that would capture the proportion of patients 18 years of age and older who have an active prescription for an opioid and have an additional opioid or benzodiazepine prescribed to them during the qualifying care encounter. This measure is being designed to reduce preventable deaths as well as reduce costs associated with the treatment of opioid-related ED use by encouraging providers to identify patients at high risk for overdose due to respiratory depression or other adverse drug events.

We are requesting public comments on this future measure concept specifically for the Hospital OQR Program setting.

In addition, in order to solicit further public comment from a wide variety of stakeholders, we will also post this measure concept to the CMS Measures Management System (MMS) Call for Public Comment Web page, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.* Readers can subscribe to receive updates through the MMS Listserv at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Listserv.html.*

7. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we continue to develop the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.*

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470), for a discussion of our policy for updating Hospital OQR Program measures, the same policy we adopted for updating Hospital IQR Program measures, which includes the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This policy expanded upon the subregulatory process for updating measures that we finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). We are not proposing any changes to our technical specifications policies.

8. Public Display of Quality Measures

Section 1833(t)(17)(E) of the Act, requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. In this proposed rule, we are formalizing our current public display practices regarding timing of public display and the preview period, as discussed in more detail below. We are also proposing how we will announce the preview period timeframes.

In the CY 2014 OPPS/ASC proposed rule and final rule with comment period (78 FR 43645 and 78 FR 75092), we stated that we generally strive to display hospital quality measures data on the *Hospital Compare* Web site as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites (78 FR 43645). Patient-level data that is chart-abstracted are updated on *Hospital Compare* quarterly, while data from claims-based measures and measures that are submitted using a Web-based tool are updated annually. Historically, preview for the April *Hospital Compare* data release typically occurs in January, preview for the July *Hospital Compare* data release typically occurs in April, preview for the October *Hospital Compare* data release typically occurs in July, and the preview for the December *Hospital Compare* data release typically occurs in October. During the preview period, hospitals have generally had approximately 30 days to preview their data.

In this proposed rule, therefore, we are proposing to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS, consistent with current practice. In addition, we are proposing that hospitals will generally have approximately 30 days to preview their data, also consistent with current practice. Lastly, moving forward, we are proposing to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs.

We are inviting public comments on our public display proposals as discussed above.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are unchanged from those adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). We are not proposing any changes to these requirements.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified procedural requirements at 42 CFR 419.46(b). We are not proposing any changes to our requirements regarding participation status.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 419.46(c).

We also refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based. Those finalized deadlines for the CY 2017 payment determination and CY 2018 payment determination and subsequent years are illustrated in the tables below.

Available at: *http://www.ncbi.nlm.nih.gov/pubmed/26143953.*

[62] Inocencio, TJ., et al. "The economic burden of opioid-related poisoning in the United States," October 2013. Available at: *http://www.ncbi.nlm.nih.gov/pubmed/23841538.*

CY 2017 PAYMENT DETERMINATION
[Transition period]

Patient encounter quarter	Clinical data submission deadline
Q3 2015 (July 1–September 30)	2/1/2016
Q4 2015 (October 1–December 31)	5/1/2016
Q1 2016 (January 1–March 31)	8/1/2016

CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Patient encounter quarter	Clinical data submission deadline
Q2 2016 (April 1–June 30)	11/1/2016
Q3 2016 (July 1–September 30)	2/1/2017
Q4 2016 (October 1–December 31)	5/1/2017
Q1 2017 (January 1–March 31)	8/1/2017

We are not proposing any changes to these policies.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

The following previously finalized Hospital OQR Program chart-abstracted measures require patient-level data to be submitted for the CY 2019 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis (NQF #0287);
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–4: Aspirin at Arrival (NQF #0286);
- OP–5: Median Time to ECG (NQF #0289);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture (NQF #0662); and
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of these measures for the CY 2014 payment determination and subsequent years.

We are not proposing any changes to our policies regarding the submission of chart abstracted measure data where patient-level data are submitted directly to CMS.

3. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years and CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112), for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. We are not proposing any changes to these policies for the CY 2019 payment determination.

However, in sections XIII.B.5.a. and b. of this proposed rule, we are proposing to adopt two claims-based measures beginning with the CY 2020 payment determination: OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and OP–36: Hospital Visits after Hospital Outpatient Surgery. The previously adopted submission requirements would also apply to these proposed measures, if they are adopted.

If these proposals are adopted, there will be a total of nine claims-based measures for the CY 2020 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material (NQF #0513);
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

We are not proposing any changes to our claims-based measures submission policies for the CY 2020 payment determination and subsequent years.

4. Proposed Data Submission Requirements for the Proposed OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years

As discussed in section XIII.B.5.c. of this proposed rule, we are proposing to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years—three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities. We note that we are making similar proposals in the ASCQR Program in section XIV.D.5. of this proposed rule.

a. Survey Requirements

The proposed survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration.

For all three modes of administration, we are proposing that data collection must be initiated no later than 21 days after the month in which a patient has a surgery or procedure at a hospital, and completed within 6 weeks (42 days) after initial contact of eligible patients begins. We are proposing that hospitals, via their CMS-approved vendors (discussed below), must make multiple attempts to contact eligible patients unless the patient refuses or the hospital/vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that hospitals, via their CMS-approved survey vendor, collect survey data for all eligible patients using the timeline established above and report that data to CMS by the quarterly deadlines established for each data collection period unless the hospital has been exempted from the OAS CAHPS Survey requirements under the low volume exemption discussed in section XIII.B.5.c.(6) of this proposed rule, above. These submission deadlines would be posted on the OAS CAHPS Survey Web site (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail below, compliance with the OAS CAHPS

Survey protocols and guidelines, including this monthly reporting requirement, will be overseen by CMS or its contractor that will receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously, all data collection and submission for the OAS CAHPS Survey measures is done at the Medicare participating hospital level, as identified by its CCN. All locations, that offer outpatient services, of each eligible Medicare participating hospital would be required to participate in the OAS CAHPS Survey. Therefore, the survey data reported using a Medicare participating hospital's CCN must include all eligible patients from all outpatient locations (whether the hospital outpatient department is on campus or off campus) of eligible Medicare participating hospital. Survey vendors acting on behalf of hospitals must submit data by the specified data submission deadlines. If a hospital's data are submitted after the data submission deadline, it will not fulfill the OAS CAHPS quality reporting requirements. We therefore strongly encourage hospitals to be fully appraised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We note that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf.* In the telephone-only and mixed mode survey administration methods, HOPDs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS expects vendors to comply with applicable law.

b. Vendor Requirements

To ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient surgical care, and is not influenced by the hospital, we are proposing that hospitals must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for hospitals, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. CAHPS survey approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204); the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510); the ESRD QIP (76 FR 70269 through 70270); the HH QRP (80 FR 68709 through 68710); and the HQRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on a hospital's behalf is available through the OAS CAHPS Survey Web site at: *https://oascahps.org.* The Web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. Hospitals will need to register on the OAS CAHPS Survey Web site (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each hospital must then administer (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey Web site as stated above.

Moreover, we are proposing to codify these OAS CAHPS Survey administration requirements for hospitals and survey vendors under the Hospital OQR Program at 42 CFR 419.46(g).

As stated previously, we encourage hospitals to participate in voluntary national implementation of the OAS CAHPS Survey that began in January 2016. This will provide hospitals the opportunity to gain first-hand experience collecting and transmitting OAS CAHPS data without the public reporting of results or Hospital OQR Program payment implications. For additional information, we refer readers to *https://oascahps.org/General-Information/National-Implementation.*

We are inviting public comments on our proposals for the data submission requirements for the five proposed OAS CAHPS Survey measures for the CY 2020 payment determination and subsequent years as discussed above.

5. Data Submission Requirements for Previously Finalized Measures for Data Submitted Via a Web-Based Tool for the CY 2019 Payment Determination and Subsequent Years

The following Web-based quality measures previously finalized and retained in the Hospital OQR Program require data to be submitted via a Web-based tool (CMS' QualityNet Web site or CDC's NHSN Web site) for the CY 2018 payment determination and subsequent years:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet Web site);
- OP–17: Tracking Clinical Results between Visits (NQF #0491) (via CMS' QualityNet Web site);
- OP–22: ED—Left Without Being Seen (NQF #0499) (via CMS' QualityNet Web site);
- OP–25: Safe Surgery Checklist Use (via CMS' QualityNet Web site);
- OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (via CMS' QualityNet Web site);
- OP–27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site) (NQF #0431);
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet Web site);
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #1536) (via CMS' QualityNet Web site); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet Web site).

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet Web site for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data (specifically, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431)) submitted via the CDC NHSN Web site.

We are not proposing any changes to our policies regarding the submission of measure data submitted via a Web-based tool.

6. Population and Sampling Data Requirements for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted. We are not proposing any changes to our population and sampling requirements.

7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding our validation requirements. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487), for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified these policies at 42 CFR 419.46(e). For the CY 2018 payment determination and subsequent years, validation is based on four quarters of data ((validation quarter 1 (January 1–March 31), validation quarter 2 (April 1–June 30), validation quarter 3 (July 1–September 30), and validation quarter 4 (October 1–December 31)) (80 FR 70524).

We are not proposing any changes to our validation requirements.

8. Proposed Extension or Exemption Process for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or exception process under the Hospital OQR Program.

In this proposed rule, we are proposing to update our extraordinary circumstances exemption (ECE) policy to extend the ECE request deadline for both chart-abstracted and Web-based measures from 45 days following an event causing hardship to 90 days following an event causing hardship. This proposal would become effective with ECEs requested on or after January 1, 2017. In the past, we have allowed hospitals to submit an ECE request form for measures within 45 days following an event that causes hardship and prevents them from providing data for measures (76 FR 74478 through 74479). In certain circumstances, however, it may be difficult for hospitals to timely evaluate the impact of certain extraordinary events within 45 days. We believe that extending the deadline to 90 days would allow hospitals more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the extraordinary circumstance in their ECE request form to CMS. For example, if a hospital has suffered damage due to a hurricane on January 1, it would have until March 31 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form.

This timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the Hospital-Acquired Condition Reduction Program (80 FR 49580), and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543). We note that in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205; 25233 through 25234), we proposed deadlines of 90 days following an event causing hardship for the Hospital IQR Program (in non-eCQM circumstances) and for the LTCH QRP Program. In section XIV.D.6. of this proposed rule, we also are proposing a deadline of 90 days following an event causing hardship for the ASCQR Program.

We are inviting public comments on our proposal to extend the submission deadline for an extraordinary circumstances extension or exemption to within 90 days of the date that the extraordinary circumstance occurred, effective January 1, 2017, for the CY 2019 payment determination and subsequent years, as discussed above.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2019 Payment Determination and Subsequent Years—Clarification

We are making one clarification to our reconsideration and appeals procedures. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524) for a discussion of our reconsideration and appeals procedures. Currently, a hospital must submit a reconsideration request to CMS via the QualityNet Web site no later than the first business day of the month of February of the affected payment year (78 FR 75118 through 75119). A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board (78 FR 75118 through 75119). Beginning with the CY 2018 payment determination, however, hospitals must submit a reconsideration request to CMS via the QualityNet Web site by no later than the first business day on or after March 17 of the affected payment year (80 FR 70524). We codified the process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) regarding appeals with the Provider Reimbursement Review Board.

In this proposed rule, we are clarifying our policy regarding appeals procedures. Specifically, if a hospital fails to submit a timely reconsideration request to CMS via the QualityNet Web site by the applicable deadline, then the hospital will not subsequently be eligible to file an appeal with the Provider Reimbursement Review Board. This clarification will be effective January 1, 2017 for the CY 2017 payment determination and subsequent years.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2017 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their

Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site): "J1," "J2," "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," or "U." Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator "S" or "T." We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2017

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2017 annual payment update factor. For the CY 2017 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 73.411 by the proposed full conversion factor of 74.909. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2017 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1," "J2," "P," "Q1," "Q2," "Q3," "Q4," "R," "S," "T," "V," and "U" (other than new technology APCs to which we have proposed status indicator assignment of "S" and "T"). We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We are inviting public comments on these proposals.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV.4. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), and section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70537) for an overview of the regulatory history of the ASCQR Program.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. We are not proposing any changes to this policy.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

We previously adopted a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; 79 FR 66967 through 66969). We are not proposing any changes to this policy.

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. We are not proposing any changes to this process.

3. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we implemented the ASCQR Program effective with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission directly to CMS via an online Web-based tool for the CY 2015 payment determination and subsequent years, and one process of care, preventive service measure submitted via an online, Web-based tool to CDC's National Health Safety Network (NHSN) for the CY 2017 payment determination and subsequent years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted three chart-abstracted measures with data submission to CMS via an online Web-based tool for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we excluded one of these measures, ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536), from the CY 2017 payment determination measure set and allowed for voluntary data collection and reporting for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted one additional claims-based measure for the CY 2018 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70537), we did not adopt any additional measures for the CY 2019 payment determination and subsequent years.

The previously finalized measure set for the ASCQR Program for the CY 2019 payment determination and subsequent years is listed below.

ASCQR Program Measure Set Previously Finalized for the CY 2019 Payment Determination and Subsequent Years

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265 †	All-Cause Hospital Transfer/Admission.
ASC–5	0264 †	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures.*
ASC–8	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

† We note that NQF endorsement for this measure was removed.

* Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

4. Proposed ASCQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to measure selection for the ASCQR Program. In this proposed rule, we are proposing to adopt a total of seven measures for the CY 2020 payment determination and subsequent years: two measures collected via a CMS Web-based tool and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. The two measures that require data to be submitted directly to CMS via a Web-based tool are: (1) ASC–13: Normothermia Outcome; and (2) ASC–14: Unplanned Anterior Vitrectomy. The five proposed survey-based measures (ASC–15a–e) are collected via the OAS CAHPS Survey. These measures are discussed in detail below.

a. ASC–13: Normothermia Outcome

(1) Background

Impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia. Perioperative hypothermia is associated with numerous adverse outcomes, including: cardiac complications;[63] surgical site infections;[64] impaired coagulation;[65] and colligation of drug effects;[66] as well as post-anesthetic shivering and thermal discomfort. When intraoperative normothermia is maintained, patients experience fewer adverse outcomes and their overall care costs are lower.[67] Several methods to maintain normothermia are available. While there is no literature currently available on variation in rates of normothermia among ASC facilities, variability in maintaining normothermia has been demonstrated in other clinical care settings.[68] This measure provides the opportunity for ASCs to improve quality of care and lower the rates of anesthesia-related complications in the ASC setting.

(2) Overview of Measure

We believe it is important to monitor the rate of anesthesia-related complications in the ASC setting because many surgical procedures performed at ASCs involve anesthesia. Therefore, we are proposing to adopt the ASC–13: Normothermia Outcome measure, which is based on aggregate measure data collected by the ASC and submitted via a CMS Web-based tool (QualityNet), in the ASCQR Program for the CY 2020 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting of measure information would make patient outcomes following procedures performed under general or neuraxial anesthesia more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities to reduce perioperative hypothermia and associated complications where necessary.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The proposed ASC–13 measure was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2014."[69] The MAP reviewed the measure (MUC ID: X3719) and conditionally supported it for the ASCQR Program, pending completion of reliability testing and NQF review and endorsement.[70] The MAP agreed that this measure is highly impactful and meaningful to patients. It stated that anesthetic-induced thermoregulatory impairment may cause perioperative hypothermia, which is associated with adverse outcomes including significant morbidity (decrease in tissue metabolic rate, myocardial ischemia, surgical site infections, bleeding diatheses, prolongation of drug effects) and mortality. As an intermediate outcome measure, the workgroup agreed that this measure moves towards an outcome measure that fills the workgroup identified gap of anesthesia-related complications.[71]

Furthermore, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC–13 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,[72] an entity recognized within the community as an expert in measure development for the ASC setting. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs, because procedures using anesthesia are commonly performed in ASCs and, as discussed above, maintenance of perioperative normothermia can signify important issues in the care being provided by ASCs. While the Normothermia Outcome measure is not NQF-endorsed, we believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the ASCQR Program. The MAP agreed that this measure "is highly impactful and meaningful to patients" and that, as an intermediate outcome measure, the Normothermia Outcome measure moves towards an outcome measure that fills the workgroup-identified gap of anesthesia-related complications. Moreover, we believe this measure is reliable because reliability testing completed by the measure steward comparing ASC-reported normothermia rates and re-abstracted normothermia rates found the difference from originally submitted and re-abstracted normothermia rates ranged from −1.6 percent to 0.9 percent, with a 95 percent confidence interval of −0.9 percent, 0.5 percent. Because this confidence interval includes zero, there is no evidence that the submitted and abstracted rates are statistically different at the $p = 0.05$ level. Therefore, we believe there is strong evidence that the Normothermia Outcome measure is reliable.

---

[63] Frank SM, Fleisher LA, Breslow MJ, et al. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. JAMA. 1997;277(14): 1127–1134.

[64] Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization: Study of wound infection and temperature group. N Engl J Med. 1996;334(19): 1209–1215.

[65] Rajagopalan S, Mascha E, Na J, Sessler DI. The effects of mild hypothermia on blood loss and transfusion requirements during total hip arthroplasty. Lancet. 1996;347(8997):289–292.

[66] Kurz A. Physiology of thermoregulation. Best Pract Res Clin Anaesthesiol.2008;22(4):627–644.

[67] Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. AANA Journal. 1999;67(2): 155–164.

[68] Frank SM, Beattie C, Christopherson R, et al. Unintentional Hypothermia is associated with Postoperative Myocardial Ischemia: The Perioperative Ischemia Randomized Anesthesia Trial Study Group. Anesthesiology 1993;78(3):468–476.

[69] National Quality Forum. List of Measures under Consideration for December 1, 2014.National Quality Forum, Dec. 2014. Available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.*

[70] National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[71] Ibid.

[72] ASC Quality Collaboration. "ASC Quality Collaboration." Available at: *http://www.ascquality.org/.*

(3) Data Sources

This measure is based on aggregate measure data collected via chart-abstraction by the ASC and submitted via a CMS Web-based tool (that is, QualityNet).

We are proposing that the data collection period for the proposed ASC–13 measure would be the calendar years 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, the data collection period would be CY 2018. We also are proposing that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2020 payment determination, the submission period would be January 1, 2019 to May 15, 2019. We refer readers to section XIV.D.3.b. of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC–13 measure is the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit (PACU). The numerator is the number of surgery patients with a body temperature equal to or greater than 96.8 degrees Fahrenheit/36 degrees Celsius recorded within 15 minutes of arrival in the PACU. The denominator is all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes in duration.

(5) Cohort

The measure includes all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes' duration.

The measure excludes: Patients who did not have general or neuraxial anesthesia; patients whose length of anesthesia was less than 60 minutes; and patients with physician/advanced practice nurse/physician assistant documentation of intentional hypothermia for the procedure performed. Additional methodology and measure development details are available at: *http://www.ascquality.org/qualitymeasures.cfm* under "ASC Quality Collaboration Measures Implementation Guide."

(6) Risk Adjustment

The measure is not risk-adjusted.

We are inviting public comments on our proposal to adopt the ASC–13: Normothermia Outcome measure for the CY 2020 payment determination and subsequent years as discussed above.

b. ASC–14: Unplanned Anterior Vitrectomy

(1) Background

An unplanned anterior vitrectomy is performed when vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. Cataracts are a leading cause of blindness in the United States, with 24.4 million cases in 2010.[73] Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.[74] While unplanned anterior vitrectomy rates are relatively low, this procedure complication may result in poor visual outcomes and other complications, including retinal detachment.[75] Cataract surgery is the most common surgery performed in ASCs; therefore, this measure is of interest to the ASC Program.[76]

(2) Overview of Measure

Based on the prevalence of cataract surgery in the ASC setting, we believe it is important to minimize adverse patient outcomes associated with cataract surgery. Therefore, we are proposing to adopt the ASC–14: Unplanned Anterior Vitrectomy measure in the ASCQR Program for the CY 2020 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of this unplanned procedure at ASCs more visible to both ASCs and patients and would incentivize ASCs to incorporate quality improvement activities to reduce the occurrence of unplanned anterior vitrectomies. The measure also addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.[77]

The ASC–14 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2014."[78] The MAP reviewed this measure (MUC ID: X3720) and conditionally supported it for the ASCQR Program, pending completion of reliability testing and NQF review and endorsement.[79] The MAP agreed that this measure is highly impactful and meaningful to patients.[80] It stated that according to the National Eye Institute report in 2002, more than half of U.S.

---

[73] National Eye Institute. "Cataracts." Cataracts. National Institutes of Health, n.d. Available at: *https://www.nei.nih.gov/eyedata/cataract#1.*

[74] "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[75] Chen M, Lamattina KC, Patrianakos T, Dwarakanathan S. Complication rate of posterior capsule rupture with vitreous loss during phacoemulsification at a Hawaiian cataract surgical center: A clinical audit. Clin Ophthamlol. 2014 Feb 5;8:375–378.

[76] "Measure Application Partnership Hospital Workgroup", National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[77] National Quality Forum. MAP 2015 Considerations for Selection of Measures for Federal Programs: Hospitals. Rep. National Quality Forum, Feb. 2015. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx.*

[78] National Quality Forum. List of Measures under Consideration for December 1, 2014.National Quality Forum, Dec. 2014. Available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.*

[79] National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[80] Ibid.

residents over 65 years have a cataract.[81] Furthermore, cataracts are a leading cause of blindness, with more than 1.5 million cataract surgeries performed annually to improve the vision of those with cataracts.[82] Unplanned anterior vitrectomy is a recognized adverse intraoperative event during cataract surgery occurring in two to four percent of all cases,[83] with some research showing that rates of unplanned anterior vitrectomy are higher among less experienced surgeons.[84] The MAP continued to state that an anterior vitrectomy, the repair of a rupture in a mainly liquid portion of the eye, is generally an unplanned complication of a cataract surgery.[85] The MAP agreed that this is an outcome measure that fills the workgroup identified priority gap of procedure complications.[86]

The proposed ASC–14 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,[87] an entity recognized within the community as an expert in measure development for the ASC setting of care. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs, because cataract surgery is commonly performed in ASCs and, as discussed above, complications such as unplanned anterior vitrectomy can signify important issues in the care being provided by ASCs. While the Unplanned Anterior Vitrectomy measure is not NQF endorsed, we believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure for use in the ASCQR Program. The MAP stated that the Unplanned Anterior Vitrectomy measure is "highly impactful and meaningful to patients" because cataracts are a leading cause of blindness among Americans and an unplanned anterior vitrectomy is a generally unplanned complication of the surgery intended to help restore patients' vision. Furthermore, we believe the measure is reliable because reliability testing performed by the measure steward found that the difference from originally submitted and re-abstracted vitrectomy rates was zero for 92 percent of ASCs reviewed. Therefore, we believe there is strong evidence that the Unplanned Anterior Vitrectomy measure is reliable.

(3) Data Sources

This measure is based on aggregate measure data collected via chart-abstraction by the ASC and submitted via a CMS Web-based tool (that is, QualityNet).

We are proposing that the data collection period for the proposed ASC–14 measure would be the calendar years 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, the data collection period would be CY 2018. We also are proposing that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2020 payment determination, the submission period would be January 1, 2019 to May 15, 2019. We refer readers to section XIV.D.3.b. of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC–14 measure is the percentage of cataract surgery patients who have an unplanned anterior vitrectomy. The numerator for this measure is all cataract surgery patients who had an unplanned anterior vitrectomy. The denominator is all cataract surgery patients.

(5) Cohort

There are no additional inclusion or exclusion criteria for the proposed ASC–14 measure. Additional methodology and measure development details are available at: *http://www.ascquality.org/qualitymeasures.cfm*, under "ASC Quality Collaboration Measures Implementation Guide."

(6) Risk Adjustment

This measure is not risk-adjusted.

We are inviting public comments on our proposal to adopt the ASC–14: Unplanned Anterior Vitrectomy measure for the CY 2020 payment determination and subsequent years as discussed above.

c. ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

(1) Background

Currently, there is no standardized survey available to collect information on the patient's overall experience for surgeries or procedures performed within an ASC. Some ASCs are conducting their own surveys and reporting these results on their Web sites, but there is not one standardized survey in use to assess patient experiences with care in ASCs that would allow valid comparisons across ASCs. Patient-centered experience of care measures are a component of the 2016 CMS Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.[88] In addition, information on patient experience with care at a provider/facility is an important quality indicator to help providers and facilities improve services furnished to their patients and to assist patients in choosing a provider/facility at which to seek care.

(2) Overview of Measures

The OAS CAHPS Survey was developed as part HHS' Transparency Initiative to measure patient experiences with ASC care.[89] In 2006, CMS implemented the Hospital CAHPS (HCAHPS) Survey, which collects data from hospital inpatients about their experience with hospital inpatient care (71 FR 48037 through 48039). The HCAHPS Survey, however, is limited to data from patients who receive inpatient care for specific diagnosis-related groups for medical, surgical, and obstetric services; it does not include patients who received outpatient surgical care from ASCs or HOPDs. Throughout the development of the OAS CAHPS Survey, CMS considered the type of data collected for HCAHPS and other existing CAHPS surveys as well as the terminology and question wording to maximize consistency across

---

[81] Ibid.

[82] Ibid.

[83] Schein OD, Steinberg EP, Javitt JC, et al. Variation in cataract surgery practice and clinical outcomes. Ophthalmology 1994;101:1142–1152; Tan JHY and Karawatowski. Phacoemulsification cataract surgery and unplanned anterior vitrectomy—is it bad news?. Eye. 2002 March;16:117–120.

[84] Tan JHY and Karawatowski. Phacoemulsification cataract surgery and unplanned anterior vitrectomy—is it bad news?. Eye. 2002 March;16:117–120.

[85] National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[86] Ibid.

[87] ASC Quality Collaboration. "ASC Quality Collaboration." Available at: *http://www.ascquality.org/.*

[88] CMS National Quality Strategy 2016. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[89] U.S. Department of Health and Human Services. *HHS Strategic Plan, Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.* Feb. 2016. Available at: *http://www.hhs.gov/about/strategic-plan/strategic-goal-4/index.html.*

CAHPS surveys. CMS has developed similar surveys for other settings of care that are currently used in other quality reporting and value-based purchasing programs, such as the Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQRP (80 FR 47141 through 47207).

The OAS CAHPS Survey contains 37 questions that cover topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey also contains two global rating questions and asks for self-reported health status and basic demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The basic demographic information captured in the OAS CAHPS Survey are standard AHRQ questions used to develop case mix adjustment models for the survey. Furthermore, the survey development process followed the principles and guidelines outlined by the AHRQ and its CAHPS® Consortium. The OAS CAHPS Survey received the registered CAHPS trademark in April 2015. OAS CAHPS Survey questions can be found at *https://oascahps.org/Survey-Materials* under "Questionnaire."

We are proposing to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years: three OAS CAHPS composite survey-based measures and two global survey-based measures (discussed below). We believe that these survey-based measures will be useful to assess aspects of care where the patient is the best or only source of information, and to enable objective and meaningful comparisons between ASCs. We note that we are making similar proposals in the Hospital OQR Program in section XIII.B.5.c. of this proposed rule. The three OAS CAHPS composite survey-based measures are:

- ASC–15a: OAS CAHPS—About Facilities and Staff;
- ASC–15b: OAS CAHPS—Communication About Procedure; and
- ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery.

Each of the three OAS CAHPS composite survey-based measures consists of six or more questions. Furthermore, the two global survey-based measures are:

- ASC–15d: OAS CAHPS—Overall Rating of Facility; and
- ASC–15e: OAS CAHPS—Recommendation of Facility.

The two global survey-based measures are comprised of a single question each and ask the patient to rate the care provided by the ASC and their willingness to recommend the ASC to family and friends. More information about these measures can be found at the OAS CAHPS Survey Web site (*https://oascahps.org*).

The five survey-based measures (MUC IDs: X3697; X3698; X3699; X3702; and X3703) we are proposing were included on the CY 2014 MUC list,[90] and reviewed by the MAP.[91] The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.[92] The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.[93] Further, the MAP stated that given that these measures are also under consideration for the Hospital OQR Program, they help to promote alignment across care settings.[94] It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient reported outcomes and patient and family engagement.[95] Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities aren't overburdened.[96]

These measures have been fully developed since submission to the MUC List. The survey development process followed the principles and guidelines outlined by the AHRQ[97] and its CAHPS® Consortium[98] in developing a patient experience of care survey, such as: reporting on actual patient experiences; standardization across the survey instrument, administration protocol, data analysis, and reporting; and extensive testing with consumers. Development also included: reviewing surveys submitted under a public call for measures; reviewing existing literature; conducting focus groups with patients who had recent outpatient surgery; conducting cognitive interviews with patients to assess their understanding and ability to answer survey questions; obtaining stakeholder input on the draft survey and other issues that may affect implementation; and conducting a field test.

In addition, we received public input from several modes. We published a request for information on January 25, 2013 (78 FR 5460) requesting information regarding publicly available surveys, survey questions, and measures indicating patient experience of care and patient-reported outcomes from surgeries or other procedures for consideration in developing a standardized survey to evaluate the care received in these facilities from the patient's perspective. Stakeholder input was also obtained through communications with a TEP comprised of experts on outpatient surgery, including clinicians, providers, patient advocates, and accreditation organizations. The TEP provided input and guidance on issues related to survey development, and reviewed drafts of the survey throughout development.

After we determined that the survey instrument was near a final form, we tested the effect of various data collection modes (that is, mail-only, telephone-only, or mail with telephone follow-up of nonrespondents) on survey responses. We began voluntary national implementation of the OAS CAHPS Survey in January 2016.[99]

In addition, while the proposed OAS CAHPS Survey-based measures are not currently NQF-endorsed, they will be submitted to the NQF for endorsement under an applicable call for measures in the near future.

In section XIX. of this proposed rule, the Hospital VBP Program is proposing to remove the three Pain Management dimension questions of the HCAHPS Survey from the total Hospital VBP Program performance score due to confusion about the intent of these questions and the public health concern about the ongoing prescription opioid overdose epidemic. For more information about the pain management questions captured in the HCAHPS Survey and their use in the Hospital

---

[90] National Quality Forum. *List of Measures under Consideration for December 1, 2014.* National Quality Forum, Dec. 2014. Available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.*

[91] National Quality Forum. *MAP 2015 Final Recommendations to HHS and CMS.* Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[92] Ibid.

[93] Ibid.

[94] Ibid.

[95] Ibid.

[96] Ibid.

[97] Agency for Healthcare Research and Quality. "Principles Underlying CAHPS Surveys." Available at: *https://cahps.ahrq.gov/about-cahps/principles/index.html.*

[98] Agency for Healthcare Research and Quality. "The CAHPS Program." Available at: *https://cahps.ahrq.gov/about-cahps/cahps-program/index.html.*

[99] Outpatient and Ambulatory Surgery CAHPS Survey. "National Implementation" Available at: *https://oascahps.org/General-Information/National-Implementation.*

VBP Program, we refer readers to section XIX.B.3. of this proposed rule.

The OAS CAHPS Survey also contains two questions regarding pain management. We believe pain management is an important dimension of quality, but realize that there are concerns about these types of questions. However, the pain management questions in the OAS CAHPS Survey are very different from those contained in the HCAHPS Survey because they focus on communication regarding pain management rather than pain control. Specifically, the OAS CAHPS Survey pain management communication questions read:

Q: Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?

☐ A1: Yes, definitely.
☐ A2: Yes, somewhat.
☐ A3: No.

Q: At any time after leaving the facility, did you have pain as a result of your procedure? [100]

☐ A1: Yes.
☐ A2: No.

Unlike the HCAHPS pain management questions, which directly address the adequacy of the hospital's pain management efforts, such as prescribing opioids, the OAS CAHPS pain management communication questions focus on the information provided to patients regarding pain management following discharge from an ASC. We continue to believe that pain control is an appropriate part of routine patient care that ASCs should manage and is an important concern for patients, their families, and their caregivers. We also note that appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. In addition, we note that, unlike the Hospital VBP Program, there is no link between scoring well on the questions and higher hospital payments. However, we also recognize that questions remain about the ongoing prescription opioid epidemic. For these reasons, we are proposing to adopt the OAS CAHPS Survey measures as described in this section, including the pain management communication questions, but will continue to evaluate the appropriateness and responsiveness of these questions to patient experience of care and public health concerns. We also welcome feedback on these pain management communication questions for use in future revisions of the OAS CAHPS Survey.

(3) Data Sources

As discussed in the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*), the survey has three administration methods: mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to section XIV.D.5. of this proposed rule for an in-depth discussion of the data submission requirements associated with the proposed OAS CAHPS Survey measures. To summarize, to meet the OAS CAHPS Survey requirements for the ASCQR Program, we are proposing that ASCs contract with a CMS-approved vendor to collect survey data for eligible patients at the ASCs on a monthly basis and report that data to CMS on the ASC's behalf by the quarterly deadlines established for each data collection period. ASCs may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions ASCs develop or use from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Q1–Q24). The list of approved vendors is available at: *https://oascahps.org*.

We also are proposing to codify the OAS CAHPS Survey administration requirements for ASCs and vendors under the ASCQR Program at 42 CFR 416.310(e), and refer readers to section XIV.D.5. of this proposed rule for more details. It should be noted that non-discrimination requirements for effective communication with persons with disabilities and language access for persons with limited English proficiency should be considered in administration of the surveys. For more information, see *http://www.hhs.gov/civil-rights*.

We are proposing that the data collection period for the OAS CAHPS Survey measures would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, ASCs would be required to collect data on a monthly basis, and submit this collected data on a quarterly basis, for January 1, 2018–December 31, 2018 (CY 2018).

We are further proposing that, as discussed in more detail below, ASCs will be required to survey a random sample of eligible patients on a monthly basis. A list of acceptable random sampling methods can be found in the OAS CAHPS Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*). We are also proposing that ASCs would be required to collect at least 300 completed surveys over each 12-month reporting period(an average of 25 completed surveys per month). We acknowledge that some smaller ASCs may not be able to collect 300 completed surveys during a 12-month period; therefore, we are proposing an exemption for facilities with lower patient censuses. ASCs would have the option to submit a request to be exempted from performing the OAS CAHPS Survey if they treat fewer than 60 survey-eligible patients during the year preceding the data collection period. We refer readers to section XIV.B.4.c.(6) of this proposed rule for details on this proposal. However, we believe it is important to capture patients' experience of care at ASCs. Therefore, except as discussed in section XIV.B.4.c.(6) of this proposed rule below, we also are proposing that smaller ASCs that cannot collect 300 completed surveys over a 12-month reporting period will only be required to collect as many completed surveys as possible during that same time period, with surveying all eligible patients (that is, no sampling). For more information regarding these survey administration requirements, we refer readers to the OAS CAHPS Survey Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*).

Furthermore, we are proposing that ASC eligibility to perform the OAS CAHPS Survey would be determined at the individual ASC level. In other words, an individual ASC that meets the exemption criteria outlined in section XIV.B.4.c.(6) of this proposed rule, below, may submit a participation exemption request form, regardless of whether it operates under an independent CCN or shares a CCN with other facilities. CMS will then assess that ASC's eligibility for a participation exemption due to facility size independent of any other facilities sharing its CCN. However, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the CCN level. Therefore, the reporting for a CCN would include all eligible patients from all eligible ASCs covered by the CCN.

(4) Measure Calculations

As noted above, we are proposing to adopt three composite OAS CAHPS Survey-based measures (ASC–15a, ASC–15b, and ASC–15c) and two global survey-based measures (ASC–15d and ASC–15e). An ASC's performance for a given payment determination year will be based upon the successful submission of all required data in accordance with the data submission requirements discussed in section XIV.D.5 of this proposed rule. Therefore, ASCs' scores on the OAS CAHPS Survey-based measures, discussed below, will not affect whether they are subject to the 2.0 percentage point payment reduction for ASCs that fail to meet the reporting requirements of the ASCQR Program. These measure calculations will be used for public reporting purposes only.

---

[100] We note that this question is a control question only used to determine if the facility should have given a patient additional guidance on how to handle pain after leaving the facility. The facility is not scored based on this question.

(A) Composite Survey-Based Measures

ASC rates on each composite OAS CAHPS Survey-based measure would be calculated by determining the proportion of "top-box" responses (that is, "Yes" or "Yes Definitely") for each question within the composite and averaging these proportions over all questions in the composite measure. For example, to assess ASC performance on the composite measure ASC–15a: OAS CAHPS—About Facilities and Staff, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (that is, six).

As a specific example, we take an ASC that had 50 surveys completed and received the following proportions of "top-box" responses through sample calculations:

- 25 "top-box" responses out of 50 total responses on Question One
- 40 "top-box" responses out of 50 total responses on Question Two
- 50 "top-box" responses out of 50 total responses on Question Three
- 35 "top-box" responses out of 50 total responses on Question Four
- 45 "top-box" responses out of 50 total responses on Question Five
- 40 "top-box" responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that facility's measure score for public reporting as follows:

$$\text{ASC Publicly Reported Score} = \frac{(0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8)}{6}$$

This calculation would give this example ASC a raw score of 0.78 or 78 percent for the ASC–15a measure for purposes of public reporting. We note that each percentage would then be adjusted for differences in the characteristics of patients across ASCs as described in section XIV.B.4.c.(7) of this proposed rule. As a result, the final ASC percentages may vary slightly from the raw percentage as calculated in the example above.

(B) Global Survey-Based Measures

We also are proposing to adopt two global OAS CAHPS Survey measures. ASC–15d asks the patient to rate the care provided by the HOPD on a scale of 0 to 10, and ASC–15e asks about the patient's willingness to recommend the HOPD to family and friends on a scale of "Definitely No" to "Definitely Yes."

ASC performance on each of the two global OAS CAHPS Survey-based measures would be calculated by proportion of respondents providing high-value responses (that is, a 9–10 rating or "Definitely Yes") to the survey questions over the total number of respondents. For example, if an ASC received 45 9- and 10-point ratings out of 50 responses, this ASC would receive a 0.9 or 90 percent raw score, which would then be adjusted for differences in the characteristics of patients across ASCs as described in section XIV.B.4.c.(7) of this proposed rule, below, for purposes of public reporting.

(5) Cohort

The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. Eligible patients, regardless of insurance or method of payment, can participate.

For purposes of each survey-based measure captured in the OAS CAHPS Survey, an "eligible patient" is a patient 18 years or older:

- Who had an outpatient surgery or procedure in an ASC, as defined in the OAS CAHPS Survey administration manual (*https://oascahps.org/Survey-Materials*);
- Who does not reside in a nursing home;
- Who was not discharged to hospice care following their surgery;
- Who is not identified as a prisoner; and
- Who did not request that ASCs not release their name and contact information to anyone other than ASC personnel.

There are a few categories of otherwise eligible patients who are excluded from the measure as follows:

- Patients whose address is not a U.S. domestic address;
- Patients who cannot be surveyed because of state regulations;
- Patient's surgery or procedure does not meet the eligibility CPT or G-codes as defined in the OAS CAHPS Survey administration manual (*https://oascahps.org/Survey-Materials*); and
- Patients who are deceased.

(6) Exemption

We understand that facilities with lower patient censuses may be disproportionately impacted by the burden associated with administering the survey and the resulting public reporting of OAS CAHPS Survey results. Therefore, we are proposing that ASCs may submit a request to be exempted from performing the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the "eligibility period," which is the calendar year before the data collection period. For example, for the CY 2020 payment determination, this exemption request would be based on treating fewer than 60 survey-eligible patients in CY 2017, which is the calendar year before the data collection period (CY 2018) for the CY 2020 payment determination. All exemption requests will be reviewed and evaluated by CMS.

To qualify for the exemption, we are proposing that ASCs must submit a participation exemption request form, which will be made available on the OAS CAHPS Survey Web site (*https://oascahps.org*) on or before May 15 of the data collection year. For example, the deadline for submitting an exemption request form for the CY 2020 payment determination would be May 15, 2018. We determined the May 15 deadline in order to align with the deadline for submitting Web-based measures, and because we believe this deadline provides ASCs with sufficient time to review the previous years' patient lists and determine whether they are eligible for an exemption based on patient population size.

We note that ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year (42 CFR 416.305(c)). For example, an ASC as identified by NPI with fewer than 240 Medicare claims in CY 2017 (for the CY 2019 payment determination year) would not be required to participate in the ASCQR Program in CY 2018 (for the CY 2020 payment determination year).

In addition, as discussed above, while ASC eligibility to perform the OAS CAHPS Survey would be determined at the individual ASC level. In other words, an individual ASC that meets the exemption criteria outlined in section XIV.B.4.c.(6) of this proposed rule, below, may submit a participation exemption request form, regardless of whether it operates under an independent CCN or shares a CCN with other facilities. However, all data collection and submission, and ultimately, also public reporting, for the OAS CAHPS Survey measures would be at the CCN level. Therefore, the reporting for a CCN would include all eligible patients from all eligible ASCs covered by the CCN.

(7) Risk Adjustment

In order to achieve the goal of fair comparisons across all ASCs, we believe it is necessary and appropriate to adjust for factors that are not directly related to ASC performance, such as patient case-mix, for these OAS CAHPS Survey measures. The survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. These factors influence how patients respond to the survey, but are beyond the control of the ASC and are not directly related to ASC performance. For more information about risk adjustment for these measures, we refer readers to: *https://oascahps.org/General-Information/Mode-Experiment*.

(8) Public Reporting

We will propose a format and timing for public reporting of OAS CAHPS Survey data in future rulemaking prior to implementation of the measures. Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, and we believe using data from this voluntary national implementation will help inform the displays for public reporting of OAS CAHPS Survey data for the ASCQR Program, we are not proposing a format or timing for public reporting of OAS CAHPS Survey data at this time.

As currently proposed, ASCs that share the same CCN must combine data for collection and submission for the OAS CAHPS Survey across their multiple facilities. These results would then be publicly reported on the *Hospital Compare* Web site as if they apply to a single ASC. To increase transparency in public reporting and improve the usefulness of the *Hospital Compare* Web site, we intend to note on the Web site instances where publicly reported measures combine results from two or more ASCs.

We are inviting public comments on our proposals as discussed above to adopt for the CY 2020 payment determination and subsequent years, the five survey-based measures: (1) ASC–15a: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility.

If these proposals are finalized, the measure set for the ASCQR Program CY 2020 payment determination and subsequent years would be as listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED AND PROPOSED FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265 †	All-Cause Hospital Transfer/Admission.
ASC–5	0264 †	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures.*
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
ASC–13	N/A	Normothermia Outcome.***
ASC–14	N/A	Unplanned Anterior Vitrectomy.***
ASC–15a	N/A	OAS CAHPS—About Facilities and Staff.***
ASC–15b	N/A	OAS CAHPS—Communication About Procedure.***
ASC–15c	N/A	OAS CAHPS—Preparation for Discharge and Recovery.***
ASC–15d	N/A	OAS CAHPS—Overall Rating of Facility.***
ASC–15e	N/A	OAS CAHPS—Recommendation of Facility.***

† We note that NQF endorsement for this measure was removed.

* Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/docs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2QnetTier2&cid=1228772475754*.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

*** New measure proposed for the CY 2020 payment determination and subsequent years.

5. ASCQR Program Measures for Future Consideration

In the CY 2013 OPPS/ASC final rule with comment period, we set forth our considerations in the selection of ASCQR Program quality measures (77 FR 68493 through 68494). We seek to develop a comprehensive set of quality measures to be available for widespread use for making informed decisions and quality improvement in the ASC setting (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based purchasing (VBP) programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer by reducing harm caused in the delivery of care; strengthen person and family engagement as partners in their care; promote effective communication and coordination of care; promote effective prevention and treatment of chronic disease; work with communities to promote best practices of healthy living; and make care affordable.

In this proposed rule, we are inviting public comments on one measure developed by the ASC Quality Collaboration for potential inclusion in the ASCQR Program in future rulemaking: the Toxic Anterior Segment Syndrome (TASS) measure.

TASS, an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery.[101] The TASS measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. Although most cases of TASS can be treated, the inflammatory response associated with TASS can cause serious damage to intraocular tissues, resulting in vision loss.[102] Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.[103] Despite a recent focus on prevention, cases of TASS continue to occur, sometimes in clusters.[104] With millions of anterior segment surgeries being performed in the United States each year, measurement and public reporting have the potential to serve as an additional tool to drive further preventive efforts.

This issue is of interest to the ASCQR Program because cataract surgery is an anterior segment surgery commonly performed at ASCs. In addition, the TASS measure addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.

The TASS measure was included on the 2015 MUC list[105] and reviewed by the MAP. The MAP conditionally supported the measure (MUC ID: 15–1047), noting the high value and urgency of this measure, given many new entrants to the ambulatory surgical center space, as well as the clustering outbreaks of TASS. The MAP cautioned that the measure should be reviewed and endorsed by NQF before adoption into the ASCQR Program, so that a specialized standing committee can evaluate the measure for scientific acceptability.[106] A summary of the MAP recommendations can be found at: *http://www.qualityforum.org/Projects/i-m/MAP/2016_Final_Recommendations.aspx.*

The TASS measure is used to assess the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The numerator for this measure is all anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The denominator for this measure is all anterior segment surgery patients. The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf.*

We are inviting public comments on the possible inclusion of this measure in the ASCQR Program measure set in the future.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on the CMS Web site, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet Web site. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We are not proposing any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In this proposed rule, we are formalizing our current public display practices regarding timing of public display and the preview period, as discussed in more detail below and proposing how we will announce the preview period timeframes.

---

[101] Centers for Disease Control and Prevention. Toxic Anterior Segment Syndrome after Cataract Surgery—Maine, 2006. MMWR Morb Mortal Wkly Rep. 2007 Jun 29;56(25):629–630.

[102] Breebaart AC, Nuyts RM, Pels E, Edelhauser HF, Verbraak FD. Toxic Endothelial Cell Destruction of the Cornea after Routine Extracapsular Cataract Surgery. Arch Ophthalmol 1990; 108:1121–1125.

[103] Hellinger WC, Bacalis LP, Erdhauser HF, Mamalis N, Milstein B, Masket S. ASCRS Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Instruments: Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments. J Cataract Refract Surg. 2007 Jun;33(6):1095–1100.

[104] Moyle W, Yee RD, Burns JK, Biggins T. Two Consecutive Clusters of Toxic Anterior Segment Syndrome. Optom Vis Sci. 2013 Jan;90(1):e11–23.

[105] *http://www.qualityforum.org/2015_Measures_Under_Consideration.aspx*, under "2015 Measures Under Consideration List (PDF)."

[106] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

Our regulations at 42 CFR 416.315 state that data that an ASC submits for the ASCQR Program will be made publicly available on a CMS Web site. We currently make the data available on at least a yearly basis and strive to publicly display data as soon as possible. Furthermore, as previously stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we are required to give ASCs an opportunity to preview their data before it is made public. Historically, preview for the April *Hospital Compare* data release typically occurs in January, preview for the July *Hospital Compare* data release typically occurs in April, preview for the October *Hospital Compare* data release typically occurs in July, and the preview for the December *Hospital Compare* data release typically occurs in October. During the preview period, ASCs have generally had approximately 30 days to preview their data.

In this proposed rule, therefore, we are proposing to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS, consistent with current practice. In addition, we are proposing that ASCs will generally have approximately 30 days to preview their data, also consistent with current practice.

Lastly, moving forward, we are proposing to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs.

We are inviting public comments on our proposals regarding the timing of public display and the preview period as discussed above.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding maintenance of a QualityNet account and security administrator for the ASCQR Program at 42 CFR 416.310(c)(1)(i). We are not proposing any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). We are not proposing any changes to these requirements.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137) for a complete discussion of the minimum thresholds, minimum case volume, and data completeness for successful reporting for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 75035), we codified our policies regarding the minimum threshold and data completeness for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(3). We also codified our policy regarding the minimum case volume at 42 CFR 416.305(c). We are not proposing any changes to these policies.

3. Requirements for Data Submitted via an Online Data Submission Tool

In this proposed rule, we are proposing changes to requirements for data submitted via a CMS online data submission tool (*QualityNet.org*). We are not proposing any changes to our policies regarding data submitted via a non-CMS online data submission tool (CDC NHSN Web site), but are summarizing those policies for context below.

a. Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (CDC NHSN Web site). We codified our existing policies regarding the data collection time periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2). Currently, we only have one measure (ASC–8: Influenza Vaccination Coverage among Healthcare Personnel) that is submitted via a non-CMS online data submission tool.

In the CY 2015 OPPS/ASC final rule with comment period, we finalized a submission deadline of May 15 of the year when the influenza season ends for ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (79 FR 66985 through 66986). We are not proposing any changes to these requirements.

b. Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the QualityNet Web site as our CMS online data submission tool: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383.*

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), we finalized the data collection time period for quality measures for which data are submitted via a CMS online data submission tool to cover services furnished during the calendar year 2 years prior to the payment determination year. We also finalized our policy that these data will be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. In the CY 2016 OPPS/ASC final rule with comment period, we codified our existing policies regarding the data collection time periods for measures involving online data submission and the deadline for data submission via a CMS online data submission tool at 42 CFR 416.310(c)(1)(ii).

In this proposed rule, we are proposing to change the submission deadline from August 15 in the year prior to the affected payment determination year to May 15 in the year prior to the affected payment determination year for all data submitted via a CMS Web-based tool in the ASCQR Program for the CY 2019 payment determination and subsequent years. We are also proposing to make a corresponding change to the regulation text at § 416.310(c)(1)(ii) to reflect this policy.

We previously proposed a similar policy to adopt a May 15 submission deadline for all data submitted via a CMS Web-based tool in the CY 2016 OPPS/ASC proposed rule (80 FR 38345). However, we did not finalize that proposal due to public comments received indicating that a May 15 deadline would increase ASC administrative burden by giving ASCs less time to collect and report data, and noting previous technical issues with data submission that required extension of the data submission deadline (80 FR 70535).

However, we believe the May 15 data submission deadline would align the ASCQR Program with the Hospital OQR Program submission deadline (80 FR 70521 through 70522) for data submitted via a CMS Web-based tool. Furthermore, the proposed submission deadlines for measures submitted via a CMS Web-based tool would align the above-listed measures with the submission deadline for ASC–8, resulting in a single deadline for all data submitted via a Web-based tool by ASCs (via CMS and non-CMS Web-based tools). We believe this single deadline would reduce the administrative burden associated with submitting and tracking multiple data submission deadlines for the ASCQR Program. In addition, we believe implementing the proposed May 15 deadline will enable public reporting of these data by December of the same year, thereby enabling us to provide the public with more up-to-date information for use in making decisions about their care. Thus, we believe the benefits of implementing the proposed May 15 submission deadline for data submitted via a CMS Web-based tool outweigh previously stated stakeholder concerns with this deadline.

Therefore, we are proposing that data collected for a quality measure for which data are submitted via a CMS online data submission tool must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year for the CY 2019 payment determination and subsequent years. For example, for the CY 2017 data collection period, ASCs have January 1, 2018 through May 15, 2018 to submit their data for the CY 2019 payment determination.

This proposal would apply to the following measures for the CY 2019 payment determination and subsequent years:

- ASC–6: Safe Surgery Checklist Use;
- ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures;
- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659); and
- ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).[107]

In addition, this proposal would apply to the following proposed measures should they be finalized for the CY 2020 payment determination and subsequent years:

- ASC–13: Normothermia Outcome, and
- ASC–14: Unplanned Anterior Vitrectomy.

Lastly, we also are proposing to make corresponding changes to the regulation at 42 CFR 416.310(c)(1)(ii) to replace the date "August 15" with the date "May 15."

We are inviting public comments on our proposals to change the data submission time period and make corresponding changes to the regulation text for data submitted via a CMS online data submission tool as discussed above.

4. Claims-Based Measure Data Requirements for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and collection periods for claims-based measures for the CY 2018 payment determination and subsequent years. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536), we codified these policies at 42 CFR 416.310(b). We are not proposing any changes to these requirements.

5. Proposed Data Submission Requirements for the Proposed ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years

As discussed in section XIV.B.4.c. of this proposed rule, above, we are proposing to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years: Three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities. We note that we are making similar proposals in the Hospital OQR Program in section XIII.B.5.c. of this proposed rule.

a. Survey Requirements

The proposed survey has three administration methods: Mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration.

For all three modes of administration, we are proposing that data collection must be initiated no later than 21 days after the month in which a patient has a surgery or procedure at an ASC and completed within 6 weeks (42 days) after initial contact of eligible patients begins. We are proposing that ASCs, via their CMS-approved vendors (discussed below), must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that ASCs, via their CMS-approved survey vendor, collect survey data for all eligible patients—or a random sample thereof—using the timeline established above and report that data to CMS by the quarterly deadlines established for each data collection period unless the ASC has been exempted from the OAS CAHPS Survey requirements under the low volume exemption discussed in section XIV.B.4.c.(6) of the proposed rule, above. These submission deadlines will be posted on the OAS CAHPS Survey Web site (*https://oascahps.org*). Late submissions will not be accepted.

---

[107] We note that ASC–11 is a voluntary measure for the CY 2017 payment determination and subsequent years. This proposal would mean that ASCs that choose to submit data for this measure also would need to submit such data between January 1 and May 15 for the CY 2018 payment determination and subsequent years.

As discussed in more detail below, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly reporting requirement, will be overseen by CMS or its contractor that will receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously, all data collection and submission for the OAS CAHPS Survey measures is done at the CCN level, and all eligible ASCs in a CCN would be required to participate in the OAS CAHPS Survey. Therefore, the survey data reported for a CCN must include all eligible patients from all eligible ASCs covered by the CCN. Survey vendors acting on behalf of ASCs must submit data by the specified data submission deadlines. If an ASC's data are submitted after the data submission deadline, it will not fulfill the OAS CAHPS quality reporting requirements. We, therefore, strongly encourage ASCs to be fully appraised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey Administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We note that the use of predictive or auto dialers in telephonic survey administration under certain circumstances is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf*. In the telephone-only and mixed mode survey administration methods, ASCs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS expects vendors to comply with applicable law.

b. Vendor Requirements

To ensure that patients respond to the survey in way that reflects their actual experiences with outpatient surgical care, and are not influenced by the ASC, we are proposing that ASCs must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for ASCs and it is our belief that an experienced survey vendor will be best able to ensure reliable results. OAS CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204), the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510), the ESRD QIP (76 FR 70269 through 70270), the HH QRP (80 FR 68709 through 68710), and the HQRP (70 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on an ASC's behalf is available through the OAS CAHPS Survey Web site at: *https://oascahps.org*. The Web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. ASCs will need to register on the OAS CAHPS Survey Web site (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each ASC must then administer (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org/Survey-Materials*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey Web site as stated above.

Moreover, we also are proposing to codify these OAS CAHPS Survey administration requirements for ASCs and survey vendors under the ASCQR Program at 42 CFR 416.310(e).

As stated previously, we encourage ASCs to participate in voluntary national implementation of the OAS CAHPS Survey that began in January 2016. This will provide ASCs the opportunity to gain first-hand experience collecting and transmitting OAS CAHPS data without the public reporting of results or ASCQR Program payment implications. For additional information, we refer readers to *https://oascahps.org/General-Information/National-Implementation*.

We are inviting public comments on our proposals for the data submission requirements for the five proposed OAS CAHPS Survey-based measures for the CY 2020 payment determination and subsequent years as discussed above.

6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140 through 75141) for a complete discussion of the ASCQR Program's procedures for extraordinary circumstance extensions or exemptions (ECE) requests for the submission of information required under the ASCQR Program.[108] In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70537), we codified our policies regarding extraordinary circumstances extensions or exemptions at 42 CFR 416.310(d).

We are proposing one modification to the ASCQR Program's extraordinary circumstances extensions or exemptions policy for the CY 2019 payment determination and subsequent years. Specifically, we are proposing to extend the time to submit a request form from within 45 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred. We believe this extended deadline is necessary, because in certain circumstances it may be difficult for ASCs to timely evaluate the impact of an extraordinary event within 45 calendar days. We believe that extending the deadline to 90 calendar days will allow ASCs more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the "event" in their forms to CMS. For example, if an ASC has suffered damage due to a hurricane on January 1, it would have until March 31 (90 days) to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form. This proposed timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the HAC Reduction Program (80 FR 49580), and the Hospital Readmissions Reduction Program (80 FR 48542). We note that, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205; 25233 through

---

[108] In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we stated that we will refer to the process as the "Extraordinary Circumstances Extensions or Exemptions" process rather than the "Extraordinary Circumstances Extensions or Waivers" process.

25234), we proposed a deadline of 90 days following an event causing hardship for the Hospital IQR Program (in non-eCQM circumstances) and for the LTCH QRP Program. In section XIII.D.8. of this proposed rule, we also are proposing a similar deadline of 90 days following an event causing hardship for the Hospital OQR Program.

In addition, we are proposing to make a corresponding change to the regulation text at 42 CFR 416.310(d)(1). Specifically, we are proposing to state that ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred.

We are inviting public comments on our proposals to extend the submission deadline for an extraordinary circumstances extension or exemption and make corresponding changes to the regulation text to reflect this policy as discussed above.

7. ASCQR Program Reconsideration Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141) for a complete discussion of the ASCQR Program's requirements for an informal reconsideration process. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70537), we finalized one modification to these requirements: That ASCs must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year. We codified this policy at 42 CFR 416.330. We are not proposing any changes to this policy.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131 through 75132) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS Web site): "A2," "G2," "P2," "R2," and "Z2," as well as the service portion of device-intensive procedures identified by "J8." We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators "A2," "G2," "J8," "P2," "R2," and "Z2." These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, certain radiology services and diagnostic tests where payment is based on the MPFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the MPFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to an ASC covered surgical procedure) will be at the lesser of the MPFS nonfacility PE RVU-based amounts or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionally reduced coinsurance liability for beneficiaries. Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

In the CY 2014, CY 2015, and CY 2016 OPPS/ASC final rules with comment periods (78 FR 75132; 79 FR 66981 through 66982; and 80 FR 70537 through 70538, respectively), we did not make any changes to these policies.

In this CY 2017 OPPS/ASC proposed rule, we are not proposing any changes to these policies.

XV. Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival

A. Background

Solid organ transplant programs in the United States are subject to a specialized system of oversight that includes: (1) An organized national system of organ donation and allocation, including a national database that allows for the tracking of transplants and transplant outcomes; (2) formalized policy development, program inspection, and peer review processes under the aegis of the Organ Procurement and Transplantation Network (OPTN); (3) Medicare Conditions of Participation (CoPs) that hold transplant programs accountable for patient and graft (organ) survival for at least 1 year after each recipient's transplant; and (4) a CMS system of onsite survey and certification for Medicare-participating transplant centers. These features mean that transplant programs have been in the vanguard of efforts to hold health care providers accountable not only for acceptable processes, but for patient outcomes as well.

Congress established the framework for a national organ transplantation system in 1984, and the Health Resources and Services Administration (HRSA) and CMS then operationalized the system as a national model of accountable care in the area of solid organ transplantation.[109] The 1984 National Organ and Transplantation Act (NOTA)[110] created the OPTN and Organ Procurement Organizations (OPOs), amongst other provisions. NOTA also required the establishment of a registry that includes such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation.[111] The Scientific Registry of Transplant Recipients (SRTR) has served this purpose since 1987. The registry supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. Data in the SRTR are collected by the OPTN from hospitals and OPOs. The SRTR contains current and past information about the full continuum of transplant activity related to organ donation and wait-list candidates, transplant recipients, and survival statistics. This information is used to help develop evidence-based policy, to support analysis of transplant programs and OPOs, and to encourage research on issues of importance to the transplant community.[112]

The SRTR contains detailed information regarding: (1) Donor characteristics (for example, age, hypertension, diabetes, stroke, and body mass index); (2) organ characteristics (for example, both warm and cold ischemic time); and (3) recipient characteristics (for example, age, race, gender, body mass index, and hypertension status). The SRTR is administered by the Chronic Disease and Research Group of the Minneapolis Medical Research Foundation under a contract with HRSA. The SRTR data are then used to construct the risk profile of a transplant program's organ transplants. The risk models allow the SRTR to calculate an expected survival rate for both patients and grafts (organs) over various periods of time.

Every 6 months, the SRTR publishes a Program Specific Report (PSR) for each transplant program. Each report covers a rolling, retrospective, 2.5-year period. For example, the PSR reports the aggregate number of patient deaths and graft failures that occurred within 1 year after each transplant patient's receipt of an organ. The PSR also compares the actual number of such events with the risk-adjusted number that would be expected, and reports the resulting ratio of observed to expected events (O/E). An observed/expected ratio of 1.0, for example, means that the transplant program's outcomes were equal to the national outcomes for a patient, donor, and organ risk profile that reasonably matched the risk profile of that particular transplant program, for the time period under consideration. An O/E ratio of 1.5 means that the patient deaths or graft failures were 150 percent of the risk-adjusted expected number.[113]

On March 30, 2007, we issued a final rule, setting out CoPs for solid organ transplant programs ("Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants" (72 FR 15198)). The CoPs for data submission, clinical experience, and outcome requirements are codified at 42 CFR 482.80 and 482.82. The regulations specified that a program would not be in compliance with the CoPs for patient and graft survival if three thresholds were all crossed: (1) The O/E ratio exceeded 1.5; (2) the results were statistically significant ($p<.05$); and (3) the results were numerically meaningful (that is, the number of observed events minus the expected number is greater than 3). If all three thresholds were crossed over in a single SRTR report, the program was determined to not be in compliance with the CMS standard.

The above three criteria were the same as those used at that time by the OPTN to "flag" programs that the OPTN considered to merit deeper inquiry with regard to transplant program performance. However, we implemented the Medicare outcomes requirements in a manner that would assure that a flagged transplant program would first have an opportunity to become engaged with the OPTN peer review process, and improve outcomes, before there was significant CMS involvement. We did so by classifying outcomes that crossed over all three thresholds in a single (most recent) SRTR report (that is, a "single flag") as a lower level deficiency (that is, a "standard-level" deficiency in CMS terms). A standard-level deficiency requires a hospital to undertake improvement efforts, but continued Medicare participation is not at risk solely due to a single standard-level deficiency. Only programs flagged twice (in two SRTR reports, including the most recent report) within a 2.5-year period have been cited for a "condition-level" deficiency where Medicare termination is at risk. Approximately 79 (29.3 percent) of the 270 transplant programs (of all types of solid organs) that were flagged once in the 8-year period from the July 2007 SRTR report through the July 2015 report were not flagged again within a 2.5-year period. The CMS "two-flag" approach for citation of a condition-level deficiency allowed an opportunity for the OPTN to take timely action after the first time a program was flagged, and allowed the transplant programs some time to work with the OPTN peer review process and possibly improve outcomes quickly. As a result, almost a third of flagged programs (29.3 percent) did not require any significant CMS involvement because they were not flagged a second time within a rolling 2.5 year period.

---

[109] Hamilton, T.E. 2009, "Accountability in Health Care—Transplant Community Offers Leadership," *American Journal of Transplantation*, Vol. 9, pp. 1287–1293.

[110] National Organ Transplant Act (NOTA; Pub. L. 98–507), codified at 42 U.S.C. 274, "Organ procurement and transplantation network."

[111] 42 U.S.C. 274a, "Scientific registry."

[112] Available at: *http://srtr.org/who.aspx.*

[113] Dickinson, D.M., Arrington, C.J., et al., 2008, "SRTR program-specific reports on outcomes: A guide for the new reader," *American Journal of Transplantation*, Vol. 8 (4 PART 2), pp. 1012–1026.

We also determined to make quality improvement the cornerstone of the CMS' enforcement of the outcomes standard.[114] Through the "mitigating factors" provisions in the regulations for transplant programs at 42 CFR 488.61(g), we allowed a 210-day period for transplant programs with a condition-level outcomes deficiency to implement substantial improvements and demonstrate compliance with more recent data than the data in the available SRTR reports. Further, for programs that were unable to demonstrate compliance by the end of the 210-day period, but were on the right track and had strong institutional support from the hospital to make the necessary improvements for achieving compliance, we generally offered to enter into a voluntary "Systems Improvement Agreement" (SIA) with that hospital. An SIA provides a transplant program with additional time (generally 12 months) during which the hospital engages in a structured regimen of quality improvement. The transplant program also had an opportunity to demonstrate compliance with the CMS outcomes requirements before the end of the SIA period. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50334 through 50344 and 50359 through 50361), we further defined the mitigating factors and SIA processes at 42 CFR 488.61(f), (g), and (h). (We note that, in section XVII.B. of this proposed rule, we discuss a proposal to make additional revisions to § 488.61(h)(2) to clarify provisions relating to a signed SIA remaining in force.)

Through July 2015, we completed the mitigating factors review process for 145 programs that had been cited for condition-level patient or graft volume or outcome requirements that fell below the relevant CMS standards. Of that number, 83 programs (57.2 percent) were approved by the end of the 210-day review process on the basis of program improvements, combined with recent outcomes from which CMS concluded that the program was in present-day compliance. Another 45 programs (31.0 percent) were offered and completed a year-long SIA, while 17 programs (11.7 percent) terminated Medicare participation. CMS tracking data indicate that approximately 90 percent of programs that engaged in an SIA were able to complete the quality improvement regimen and continue Medicare participation after the end of the SIA period.

One-year post-transplant outcomes have improved since 2007 for all organ types. We believe this is partly due to the improvement efforts of both high-performing and low-performing transplant programs, and efforts of the larger transplant community itself, whose members have demonstrated a track record of consistent improvement, innovation, and research. Such community-wide endeavors, combined with OPTN and CMS work with the lowest-performing transplant centers, have resulted in 1-year post-transplant survival rates that are among the highest in U.S. history for all types of solid organs. For adult kidneys, 1-year graft survival increased nationally from 92.9 percent in CY 2007 to 94.8 percent in 2014, while 1-year patient survival increased nationally from 96.4 percent to 96.9 percent. During this time, 1-year patient survival increased nationally for heart recipients from 88.5 percent to 89.5 percent, for liver recipients from 87.7 percent to 90.8 percent, and for lung recipients from 80.4 percent to 85.7 percent.

Because the CMS outcomes requirement is based on a transplant program's outcomes in relation to the risk-adjusted national average, as national outcomes have improved, it has become much more difficult for an individual transplant program to meet the CMS outcomes standard. This is explained in more detail later in this proposed rule. We are concerned that transplant programs may elect not to use certain available organs out of fear that such use would adversely affect their outcome statistics. We observed, for example, that the percent of adult kidneys donated and recovered—but not used—increased from 16.6 percent in CY 2006 to 18.3 percent in CY 2007 to 18.7 percent in CY 2014 and 19.3 percent in CY 2015. Even if the number of recovered adult kidneys had remained the same, these percentages of unused kidneys would be of concern. However, the number of recovered kidneys is also increasing, thereby enlarging the impact of the discard rate. The combined effect of (a) more recoveries and (b) a higher percent of unused organs means that the absolute number of recovered but unused adult kidneys increased from 2,632 in CY 2007, for example, to 2,888 in CY 2014 and to 3,159 in CY 2015.

We appreciate that some of the single-year sharp increase in the percent of unused adult kidneys that occurred between CY 2006 and CY 2007 (from a previously consistent 16.6 percent rate in the 3 years prior to 2007, to 18.3 percent in 2007) may have been due to many factors, and not just any potential impact that the new CMS outcomes CoP may have had. The CMS regulation, for example, was gradually phased in. The regulation did not take effect until June 28, 2007, and transplant programs had until December 26, 2007 to register with CMS for certification under the new regulation. Other changes also occurred in 2007 that may have had a substantial impact.

In particular, in December 2006, the UNOS, under contract with HRSA, made a new OPTN organ donor data collection and matching system available for voluntary use and improved the data in the system. The OPTN voted to make such use mandatory effective April 30, 2007. The stated goal of the system was to "facilitate and expedite organ placement." [115] The system provided for a national list to be generated for each organ, with offers made to patients at transplant centers based on the order of patients on this list. The design of the system made it possible to send multiple offers simultaneously to different transplant progrms, in priority order. As the authors of a later study concluded, "This initially led to an extraordinary increase in the volume of unwanted offers to many centers"[116]

---

[114] Hamilton, T.E. 2008, "Improving Organ Transplantation in the U.S.—A Regulatory Perspective," *American Journal of Transplantation*. Vol. 8 (12), pp. 2404–2405.

[115] Massie AB, Zeger SL, Montgomery RA, Segev DL. The effects of DonorNet 2007 on kidney distribution equity and efficiency. *American Journal of Transplantation*, Vol. 9, pp. 1550–1557.

However, with substantial feedback from transplant programs, the system was improved and provided transplant programs with much more information regarding the available organs and donor characteristics. For example, the system allowed for programs to add more screening criteria, such as differentiation between local and import (for example, national) values, and screening for donors after cardiac death (DCD) with differentiation between local and import offers. In 2008, additional screening features were added, such as maximum acceptable cold ischemic time (CIT), maximum donor body mass index (BMI), and donor history of hypertension, diabetes, coronary artery disease, among others. Such improvements were designed to allow centers to restrict organ offers to those individuals who the program was most likely to accept. After the introduction of such additional system improvements, the percent of adult kidneys from deceased donors, that were not used, held at an average of 18.2 percent over the next 4 years. More recently, however, the average discard rate has resumed an upward trend, rising to 18.7 percent in CY 2014 and 19.3 percent in CY 2015. We are not aware of any studies that have specifically examined transplant program organ acceptance and discard patterns in relation to their perceptions regarding the CMS organ transplant CoPs. However, we believe that the increased percent of unused adult kidneys, combined with an increase in the number of recovered organs, creates an imperative to action, given the lifesaving benefits of organ transplantation.

Further concerns arise when we examine the use of what historically have been known as "expanded criteria donor (ECD)" organs. ECD organs are organs that are deemed transplantable but experience lower rates of functional longevity compared to most other organs. Characteristics that historically defined an ECD kidney include age of donor at or greater than 60 years, or organs from donors who were aged 50–59 years who also had experienced two of the following: Cerebrovascular accident as the cause of death; preexisting hypertension; or terminal serum creatinine greater than 1.5 mg/dl.

Although the SRTR risk-adjustment methods take into account the factors that comprise an ECD designation, ECD kidneys have been the only category of adult kidneys that experienced a decline in the number that were recovered for organ transplantation, from 3,249 in CY 2007 to 2,833 in CY 2015. Acceptance rates for ECD kidneys also declined, from 56.2 percent in CY 2007 to 51.0 percent in CY 2015. There is some evidence that this decline is influenced by other factors, such as the higher costs to the hospital that are associated with ECD organ use. ECD organ selection also requires greater sophistication on the part of a transplant program to be able, in a timely manner, to distinguish between the finer features of an ECD organ that might be appropriate to use compared with one that involves too much risk. Therefore, ECD organ use may have been a particularly sensitive indicator of risk aversion. We note that, in 2014, the OPTN replaced the ECD organ designations and implemented a more sophisticated system of adult kidney classification (the kidney donor profile index, KDPI). We believe this new system should help in the decision-making process for organ acceptance, but may have limited effect on undue risk aversion.

B. Proposed Revisions to Performance Thresholds

For the reasons described above, we are proposing to change the performance threshold at §§ 482.80(c)(2)(ii)(C) and 482.82(c)(2(ii)(C) from 1.5 to 1.85. We stated in the preamble of the March 30, 2007 final rule (72 FR 15220) that "If we determine in the future that any of the three thresholds is too low or too high, we will propose changes in the threshold through the rulemaking process." In this proposed rule, we are following through on that commitment.

The current relevant standard specifies that outcomes would not be acceptable if the ratio of observed patient deaths or graft failures divided by the risk-adjusted expected number, or "O/E," exceeds 1.5. The expected number is based on the national average, adjusted for the patient, organ, and donor risk profile of a transplant program's actual clientele for individuals who received a transplant in the 2.5-year period under consideration in each SRTR report. As the national performance has improved, it has become more difficult for transplant programs to maintain compliance with this CoP. In 2007, for example, an adult kidney transplant program was in compliance with the CMS outcomes standard if there were no more than 10.7 graft losses within one year out of 100 transplants. By 2014, that number had decreased to 7.9, a 26-percent reduction in graft losses 7 years later. Similarly, the number of patient deaths that could occur while maintaining compliance with the CoP declined from 5.4 to 4.6 out of every 100 adult kidney transplant recipients. We believe that a change in the threshold from 1.5 to 1.85 would restore the approximate compliance levels for adult kidney transplants that were allowed in 2007 when national performance was not so high. More specifically, a 1.85 threshold would mean that up to 9.7 graft losses out of 100 transplants (within 1 year of transplant) would remain within the new CMS outcomes range (which is slightly fewer than the 10.7 allowed in 2007 but more than the 7.9 allowed in 2015), and up to 5.7 patient deaths out of 100 transplants (within one year of transplant) would remain within the CMS range (compared to 5.4 in 2007 and 4.6 in 2015). Through restoring rough parity to 2007 graft failure rates, we hope to encourage transplant centers to use more of the increasing number of viable organs.

For consistency and to avoid unneeded complexity, we are proposing to use the same 1.85 threshold for all organ types and for both graft and patient survival. We appreciate that a case could instead be made for having different thresholds for different organ types, or a different threshold for graft versus patient survival. For example, if the only consideration was to restore the 2007 effective impact, the threshold for patient survival on the part of heart transplant recipients would be changed to 1.63, while the liver and lung threshold would be 2.00. Similarly, the new threshold for adult kidney graft survival would be 2.02 but for adult kidney patient survival a new threshold would be 1.77. Arguments also may be made for a variety of other thresholds, such as keeping the 1.5 threshold for heart, liver, and lung, on the grounds that there is more statistical room for improvement in outcomes for those types of organs compared to rates for adult kidney survival (which are already quite high). However, instead of a myriad of thresholds, we are proposing to adopt a consistent 1.85 threshold for all organ types, and for both graft and patient survival. This is a number that is approximately mid-range between the number that would restore the adult kidney graft tolerance range to the 2007 level, and the number that would do so for adult kidney patient survival. We believe this approach is less confusing than the alternatives, and that it would be advisable to implement the new 1.85 threshold now in a consistent and clear manner, and then to study the effects, before proceeding further. For future consideration, we also may explore other approaches that are aimed at optimizing the effective use of available organs instead of adjusting the CMS outcomes threshold further, such as the potential that a balancing measure (focused specifically on effective use of organs) may be appropriate (which we discuss in section XXIII. (Economic Analyses) of this proposed rule).

---

[116] Gerber DA., Arrington CJ, Taranto SE., Baker T, Sung RS. DonorNet and the Potential Effects on Organ Utilization. *American Journal of Transplantation*, Vol. 10, pp. 1081–1089. Article first published online: 22 MAR 2010. DOI: 10.1111/j.1600–6143.2010.03036.x.

We also note that the OPTN is examining its own flagging criteria under its new Bayesian methodology, out of concern that the OPTN may be flagging an excessive number of programs for review and contributing to undue risk aversion. The OPTN Bayesian methodology has resulted in more programs being flagged than are cited by CMS. We view this as a purposeful and desirable positioning of CMS as a backstop to the OPTN. We believe that our proposed change in this proposed rule would help ensure that, if OPTN also changed its criteria for outcomes review and as a result flagged fewer programs, those programs that are then flagged would still have the opportunity to first engage with the peer review process of the OPTN and might never be in a situation of being cited by CMS.

We are inviting public comment on this issue. Specifically, we are inviting comment on whether this proposal is effectively balancing our dual goals of improved beneficiary outcomes and increased beneficiary access. We also reiterate our statement from the March 30, 2007 final rule, that if we find that the thresholds are too low or too high, we will propose changes in future rulemaking.

XVI. Organ Procurement Organizations (OPOs): Changes to Definitions; Outcome Measures; and Documentation Requirements

A. Background

1. Organ Procurement Organizations (OPOs)

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs are available to seriously ill patients who are on a waiting list for an organ transplant. OPOs are responsible for the identification of eligible donors, recovering organs from deceased donors, reporting information to the UNOS and OPTN, and compliance with all CMS outcome and process performance measures.

2. Statutory Provisions

Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Among other provisions, section 1138(b) of the Act also specifies that an OPO must operate under a grant made under section 371(a) of the Public Health Service Act (PHS Act) or must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO within a certain time period. Congress has provided that payment may be made for organ procurement cost ‘‘only if’’ the OPO meets the performance related standards prescribed by the Secretary. Under these authorities, we established Conditions for Coverage (CfCs) for OPOs that are codified at 42 CFR part 486 and set forth the certification and recertification processes for OPOs.

Section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions that she is charged with performing under the Act. Moreover, section 1871 of the Act gives the Secretary broad authority to establish regulations that are necessary to carry out the administration of the Medicare program.

3. HHS Initiatives Related to OPO Services

The Advisory Committee on Organ Transplantation (ACOT) was established under the authority of section 222 of the PHS Act, as amended, and regulations under 42 CFR 121.12. A 2012 recommendation by ACOT stated: ‘‘ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and TC representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs.’’ [117]

4. Requirements for OPOs

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act and the PHS Act. Among other requirements, the OPO must be certified or recertified by the Secretary as an OPO. To receive payment from the Medicare and Medicaid programs for organ procurement costs, the entity must have an agreement with the Secretary. In addition, under section 1138(b) of the Act, an OPO must meet performance standards prescribed and designated by the Secretary. Among other things, the Secretary is required to establish outcome and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. An OPO must be a member of and abide by the rules and requirements of the OPTN that have been approved by the Secretary (section 1138(b)(1)(D) of the Act; 42 CFR 486.320).

B. Proposed Provisions

1. Definition of ‘‘Eligible Death’’

OPOs submit donor data to the SRTR on a continuous basis. The OPTN establishes the types and frequencies of the data to be submitted by the OPOs to the SRTR through its policies. The OPTN and SRTR collect and analyze the data pursuant to the HRSA mission to increase organ donation and transplantation. Periodically, the OPTN revises its OPO data reporting policies based on methodologies and clinical practice improvements that enable them to draw more accurate conclusions about donor and organ suitability for transplantation. When the CMS OPO regulations were published on May 31, 2006, the definition for ‘‘eligible death’’ at § 486.302 was in alignment with the OPTN definitions at that time. This ‘‘eligible death’’ definition has been used by CMS since May 31, 2006 to calculate and determine compliance with the OPO outcomes measures at § 486.318.

The OPTN has approved a change to its ‘‘eligible death’’ definition, which is scheduled to go into effect on January 1, 2017. The changes to the OPTN definition[118] are predicted to increase the availability of transplantable organs by: Increasing the maximum age for donation from 70 years of age to 75; replacing the automatic exclusion of patients with Multi-System Organ Failure (MSOF) with clinical criteria for each organ type that specifies such type's suitability for procurement; and implementing policies allowing recovery and transplantation of organs from an HIV positive donor into an HIV positive recipient, consistent with the Hope Act.[119]

---

[117] Available at: *http://www.organdonor.gov/legislation/acotrecs55.html.*

The existing definition of "eligible death" under the May 31, 2006 CfCs (71 FR 31046 through 31047; 42 CFR 486.302) would not be consistent with this OPTN revised definition. Existing § 486.302 defines this term as "the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy, independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice . . . ," and who does not exhibit active infections or other conditions, including HIV. The definition also sets out several additional general exclusion criteria, including MSOF. If there are inconsistent definitions, the resultant changes in data reported to the OPTN by the OPOs, would inhibit the SRTR's ability to produce the data required by CMS to evaluate OPO conformance with § 486.318.

Therefore, in order to ensure more consistent requirements, we are proposing to replace the current definition for "eligible death" at § 486.302 with the upcoming revised OPTN definition of "eligible death." The CMS definition would be revised to include donors up to the age of 75 and replace the automatic exclusion of potential donors with MSOF with the clinical criteria listed in the definition, that specify the suitability for procurement. We request public comments on our proposed definition. If, as a result of the public comments we receive on this proposal, additional changes are necessary to this definition, we will work with the OPTN to harmonize the definition.

2. Aggregate Donor Yield for OPO Outcome Performance Measures

At the time of publication of the May 31, 2006 OPO regulations, outcome measures specified at §§ 486.318(a)(3)(i) and (ii) and §§ 486.318(b)(3)(i) and (ii) were consistent with yield calculations then utilized by the SRTR. These CMS standards measure the number of organs transplanted per standard criteria donor and expanded criteria donor (donor yield). We have received feedback that the use of this measure has created a hesitancy on the part of OPOs to pursue donors for only one organ due to the impact on the CMS yield measure.

In 2014, the SRTR, based upon the use of empirical data, changed the way it calculates aggregate donor yield after extensive research and changes to risk-adjustment criteria. The revised metric, currently in use by the OPTN/SRTR, risk-adjusts based on 29 donor medical characteristics and social complexities. We believe the OPTN/SRTR yield metric accurately predicts the number of organs that may be procured per donor, and each OPO is measured based on the donor pool in its DSA. This methodology is a more accurate measure for organ yield performance and accounts for differences between donor case-mixes across DSAs.

Therefore, we are proposing to revise our regulations at § 486.318(a)(3) and § 486.318(b)(3) to be consistent with the current OPTN/SRTR aggregate donor yield metric. We also intend to revisit and revise the other OPO measures at a future date.

3. Organ Preparation and Transport-Documentation With the Organ

We are proposing to revise § 486.346(b), which currently requires that an OPO send complete documentation of donor information to the transplant center along with the organ. The regulation specifically lists documents that must be copied and sent by the OPO to include: Donor evaluations; the complete record of the donor's management; documentation of consent; documentation of the pronouncement of death; and documentation for determining organ quality. This requirement has resulted in an extremely large volume of donor record materials being copied and sent to the transplant centers by the OPOs with the organ. However, all these data can now be accessed by the transplant center electronically. The OPOs utilize an intercommunicative Web-based system to enter data that may be received and reviewed electronically by transplant centers.

Therefore, we are proposing to revise § 486.346(b) to no longer require that paper documentation, with the exception of blood typing and infectious disease information, be sent with the organ to the receiving transplant center. We also are proposing a revision to § 486.346(b) to make it consistent with current OPTN policy at 16.5.A,[120] which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ. The reduction in the amount of hard copy documentation that is packaged and shipped with each organ would increase OPO transplant coordinators' time, allowing them to focus on donor management and organ preparation. This proposal would not restrict the necessary donor information sent to transplant hospitals because all other donor information can be accessed electronically by the transplant center.

XVII. Transplant Enforcement Technical Corrections and Proposals

A. Technical Correction to Transplant Enforcement Regulatory References

We are proposing a technical correction to preamble and regulatory language we recently adopted regarding enforcement provisions for organ transplant centers. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50338), we inadvertently made a typographical error in the final citations in a response to a commenter and stated, "[i]n the final regulation, at § 488.61(f)(1) and elsewhere, we therefore limit the mitigating factors provision to deficiencies cited for noncompliance with the data submission, clinical experience, or outcomes requirements specified at § 488.80 and § 488.82." However, the transplant center data submission, clinical experience, and outcomes requirements are actually specified at 42 CFR 482.80 and 482.82, and not within part 488; moreover, part 488 does not contain a § 488.80 or § 488.82. We wish to correct this typographical error; the response should read as follows: "In the final regulation, at § 488.61(f)(1) and elsewhere, we therefore limit the mitigating factors provision to deficiencies cited for noncompliance with the data submission, clinical experience, or outcomes requirements specified at § 482.80 and § 482.82."

We also are proposing to amend § 488.61(f)(1) which was added in that final rule (79 FR 50359) to correct the same incorrect citations.

---

[118] Alcorn, James B. (2013). "Summary of actions taken at OPTN/UNOS Board of Directors Meeting: June 24–25, 2013." Available at: *https://optn.transplant.hrsa.gov/media/1277/policynotice_20130701.pdf.*

[119] HIV Organ Policy Equity Act, Public Law 113–51 (November 21, 2013).

[120] OPTN Policies. Policy Number 16.5.A. Organ Documentation. Effective date 4/14/2016: Page 200. Available at: *https://optn.transplant.hrsa.gov/governance/policies/.*

B. Other Proposed Revisions to § 488.61

Under current § 488.61(f)(3), transplant programs must notify CMS of their intent to request mitigating factors approval within 10 days and the time period for submission of mitigating factor materials is 120 days. Current § 488.61(f)(3) does not specify how these time periods are to be computed.

We are proposing to amend § 488.61(f)(3) to extend the due date for programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days, and to clarify that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days).

In addition, as part of our improvement efforts, in this proposed rule, we are proposing to revise § 488.61(h)(2) to clarify that a signed SIA with a transplant program remains in force even if a subsequent SRTR report indicates that the transplant program has restored compliance with the Medicare CoPs, except that CMS, in its sole discretion, may shorten the timeframe or allow modification to any portion of the elements of the SIA in such a case.

XVIII. Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

A. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), which included the Health Information Technology for Economic and Clinical Health Act (HITECH Act), amended Titles XVIII and XIX of the Act to authorize incentive payments and Medicare payment adjustments for eligible professionals (EPs), eligible hospitals, critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified EHR technology (CEHRT). Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and CAHs respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated EHR reporting periods. For a more detailed explanation of the statutory basis for the Medicare and Medicaid EHR Incentive Programs, we refer readers to the July 28, 2010 Stage 1 final rule titled, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule" (75 FR 44316 through 44317).

In the October 16, 2015 **Federal Register**, we published a final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017" (80 FR 62761 through 62955), hereinafter referred to as the "2015 EHR Incentive Programs Final Rule." [121] That final rule in part aligned the Modified Stage 2 measures with Stage 3 measures, aligned EHR reporting periods with the calendar year, and aligned aspects of the EHR Incentive Programs with other CMS quality reporting programs.

In the May 9, 2016 **Federal Register**, we published the "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models" proposed rule (81 FR 28161 through 28586), hereinafter referred to as the "2016 MIPS and APMs Proposed Rule," which included proposals under which the use of CEHRT by MIPS eligible clinicians would be evaluated under the advancing care information performance category of the MIPS as required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (81 FR 28215 through 28233). If these proposals were to be finalized, the requirements for MIPS eligible clinician EHR use and reporting for the advancing care information performance category for MIPS would be different from the requirements of meaningful use for eligible hospitals and CAHs as established in the 2015 EHR Incentive Programs Final Rule. For a full discussion of our proposals for MIPS and its impacts on requirements for MIPS eligible clinicians relating to EHR use and reporting, we refer readers to the 2016 MIPS and APMs Proposed Rule (81 FR 28215 through 28233).

B. Summary of Proposals Included in This Proposed Rule

We are proposing to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Modified Stage 2 and Stage 3 for 2017 and subsequent years. We are also proposing to reduce the thresholds of a subset of the remaining objectives and measures in Modified Stage 2 for 2017 and in Stage 3 for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, as described in section XVIII.C. of this proposed rule. These proposed changes would not apply to eligible hospitals and CAHs that attest to meaningful use under their State's Medicaid EHR Incentive Program. These eligible hospitals and CAHs would continue to attest to their State Medicaid agencies on the measures and objectives finalized in the 2015 EHR Incentive Programs Final Rule. We have chosen to limit these proposed changes to Medicare only because we are concerned that States would have to implement major process changes within a short period of time if the changes were to apply to Medicaid, including the burden of updating technology and reporting systems, which would incur both additional cost and time.

We are proposing to change the EHR reporting period in 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive Programs as described in section XVIII.D. of this proposed rule.

We are proposing to require EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year and are seeking to demonstrate meaningful use for the first time in 2017 to avoid the 2018 payment adjustment by attesting by October 1, 2017 to attest to the Modified Stage 2 objectives and measures as described in section XVIII.E. of this proposed rule.

We are proposing a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017, as well as an application process, as described in section XVIII.F. of this proposed rule.

We are proposing to change the policy on measure calculations for actions outside the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs as described in section XVIII.G. of this proposed rule. Specifically, for all meaningful use measures, unless otherwise specified, we are proposing that actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs.

---

[121] We also published two correction notices for the 2015 EHR Incentive Programs Final Rule, making corrections and correcting amendments (81 FR 11447 through 11449; 81 FR 34908 through 34909).

We believe that these proposals would result in continued advancement of certified EHR technology utilization, particularly among those EPs, eligible hospitals and CAHs that have not previously achieved meaningful use, and result in a program more focused on supporting interoperability and data sharing for all participants under the Medicare and Medicaid EHR Incentive Programs. We discuss these proposals in detail in the following sections.

C. Proposed Revisions to Objectives and Measures for Eligible Hospitals and CAHs

We are making two proposals regarding the objectives and measures of meaningful use for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. One of these proposals would eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2017 and subsequent years in an effort to reduce reporting burden for eligible hospitals and CAHs. The second proposal would reduce the reporting thresholds for a subset of the remaining Modified Stage 2 objectives and measures for 2017 and Stage 3 objectives and measures for 2017 and 2018 to Modified Stage 2 thresholds. We note that the Stage 3 Request/Accept Patient Care Record Measure under the Health Information Exchange objective is a new measure in Stage 3, therefore the proposed reduction in the threshold is not based on Modified Stage 2 thresholds.

In this proposed rule, our goal is to propose changes to the objectives and measures of meaningful use that we expect would reduce administrative burden and enable hospitals and CAHs to focus more on patient care.

1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

We are proposing to amend 42 CFR 495.22 (by revising section 495.22(e) and by adding a new section 495.22(f)) and by revising 42 CFR 495.24) to eliminate the CDS and CPOE objectives and associated measures (currently found at 42 CFR 495.22(e)(2)(iii) and (e)(3)(iii)) and 42 CFR 495.24(d)(3)(ii) and (d)(4)(ii)) for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program beginning with the EHR reporting period in calendar year 2017. For the reasons stated above, this proposal would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. In the 2015 EHR Incentive Programs Final Rule (80 FR 62782 through 62783) we finalized a methodology for evaluating whether objectives and measures have become topped out and, if so, whether a particular objective or measure should be considered for removal from the EHR Incentive Program. We apply the following two criteria, which are similar to the criteria used in the Hospital IQR and Hospital VBP Programs (79 FR 50203): (1) Statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold. In applying these criteria to the objectives and measures for Modified Stage 2 and Stage 3, we have determined that the CPOE objective and measures are topped out. We performed a significance test using 2015 attestation data to determine the performance rate at the 75th and 99th percentile. The result of this statistical analysis proved that the performance for this objective and the associated measures were over 90 percent. Using the same attestation data, we performed an analysis at the 25th, 50th, and 75th percentiles to determine the distribution regarding the percentage above the required thresholds attested by eligible hospitals and CAHs. Eligible hospitals and CAHs at the 25th percentile have attested to performance rates of over 75 percent for the measures associated with this objective. Eligible hospitals and CAHs at the 50th percentile have attested to performance rates of over 87 percent for the measures associated with this objective. Eligible hospitals and CAHs at the 75th percentile have attested to performance rates of over 95 percent for the measures associated with this objective. Therefore, based on these criteria, we consider the CPOE objective and measures topped out. Based on the 2015 attestation data, we believe that these objectives and measures have widespread adoption among eligible hospitals and CAHs and we are proposing to remove them from the Medicare EHR Incentive Program to reduce hospital administrative burden.

We also are proposing to remove the CDS objective and its associated measures for eligible hospitals and CAHs; however, these measures do not have percentage-based thresholds (hospitals attest "yes/no" to these measures) and thus do not have performance distribution that can be measured by statistical analysis. For these measures, we note that 99 percent of eligible hospitals and CAHs have attested "yes" to meeting these measures based on attestation data for 2015. We believe that the high level of successful attestation indicates achievement of widespread adoption of this objective and measures among eligible hospitals and CAHs, and that the objective and measures are no longer useful in gauging performance. Therefore, we consider this objective and measures to be "topped out" and are proposing to remove them from the Medicare EHR Incentive Program to reduce hospital administrative burden. In addition, eligible hospitals and CAHs may continue to independently measure and track activities related to the CDS objective and measures for their own quality improvement goals or preferences as the functionality will continue as part of the 2015 Edition of CEHRT. For more information on the performance data used to determine the topped out measures we refer readers to the EHR Incentive Programs Objective and Measure Performance Report by Percentile available at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

In the 2015 EHR Incentive Programs Final Rule, we also established that, for measures that were removed, the technology requirements would still be a part of the definition of CEHRT. For example, in the 2015 EHR Incentive Programs Final Rule, the Stage 1 Objective to Record Demographics was removed, but the technology and standard for this function in the EHR is still required (80 FR 62784) as a part of CEHRT. We note that the CDS and CPOE objectives and associated measures that we are proposing to remove for eligible hospitals and CAHs would still be required as part of the eligible hospital or CAH's CEHRT. However, eligible hospitals and CAHs attesting to meaningful use under Medicare would not be required to report on those measures under this proposal.

We are inviting public comments on our proposals.

2. Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018

In the 2015 EHR Incentive Programs Final Rule (80 FR 62762 through 62955), we finalized certain thresholds for the objectives and measures adopted for eligible hospitals and CAHs. In this proposed rule, we are proposing to reduce a subset of the thresholds for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for EHR reporting periods in calendar year 2017 for Modified Stage 2 and in calendar year 2017 and 2018 for Stage 3. For the reasons stated above, this proposal would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. We believe this proposal would reduce the hospital and CAH reporting burden, allowing eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program to focus more on providing quality patient care, as well as focus on updating and optimizing CEHRT functionalities to sufficiently meet the requirements of the EHR Incentive Program and prepare for Stage 3 of meaningful use. We have received correspondence from numerous hospital associations and health systems after the publication of the 2015 EHR Incentive Programs Final Rule specifically expressing concerns that they have had to resort to workarounds and processes that they believe do not add value for their patients in order to meet the current objective and measure thresholds. In the measure specifications outlined below, we are proposing to reduce a subset of the reporting thresholds to the Modified Stage 2 thresholds, as previously stated. For example, in the 2015 EHR Incentive Programs Final Rule, we finalized a threshold of more than 35 percent for the Stage 3 Patient Specific Education measure (42 CFR 495.24(d)(5)(ii)(B)(*2*)). In this proposed rule, we are proposing to reduce that threshold for 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program to more than 10 percent (proposed 42 CFR 495.24(c)(5)(ii)(B), which aligns with the Modified Stage 2 threshold for this same measure.

We note that section 1886(n)(3)(A) of the Act requires the Secretary to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use. We intend to adopt more stringent measures in future rulemaking and will continue to evaluate the program requirements and seek input from eligible hospitals and CAHs on how the measures could be made more stringent in future years of the EHR Incentive Programs. However, for the reasons discussed in further detail below, at this time we believe reducing the thresholds of certain existing measures would reduce unnecessary reporting burden and enable eligible hospitals and CAHs to focus more on patient care.

a. Proposed Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017

For EHR reporting periods in calendar year 2017, we are proposing to modify the threshold of the Modified Stage 2 View, Download, Transmit (VDT) measure under the Patient Electronic Access objective established in the 2015 EHR Incentive Programs Final Rule (80 FR 62846 through 62848), and this proposed modification would apply to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. We also are proposing to update the Modified Stage 2 measures with a new naming convention to allow for easier reference to a given measure, and to align with the measure nomenclature proposed for the MIPS. For the reasons stated above, these proposals would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program.

Specifically, we are proposing to revise section 495.22(e) to specify that the current Modified Stage 2 meaningful use objectives and measures apply for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2015 through 2017, and for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2015 and 2016. We are proposing to add a new section 495.22(f) that includes the meaningful use objectives and measures with the proposed modifications discussed below that would be applicable only to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for an EHR reporting period in calendar year 2017. We are also proposing a new naming convention for certain measures (shown in the table summarizing the Proposed Modified Stage 2 Objectives and Measures in 2017 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, below) as well as minor conforming changes to sections 495.22(a), (c)(1), and (d)(1).

Patient Electronic Access (VDT) (Proposed 42 CFR 495.22(f)(8)(ii)(B))

View Download Transmit (VDT) Measure: At least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- Denominator: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.
- Numerator: The number of patients (or patient-authorized representatives) in the denominator who view, download, or transmit to a third party their health information.
- Threshold: The numerator and denominator must be reported and the numerator must be equal to or greater than 1.
- Exclusion: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.
- Proposed Modification to the VDT Measure Threshold.

For eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we are proposing to reduce the threshold of the VDT Measure from more than 5 percent to at least one patient. We are proposing to reduce the threshold because we have heard from stakeholders including hospitals and hospital associations that they have faced significant challenges in implementing the objectives and measures that require patient action. These challenges include, but are not limited to, patients who have limited knowledge of, proficiency with, and access to information technology, as well as patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform. We recognize that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology and believe that reducing the threshold for 2017 would provide additional time for eligible hospitals and CAHs to determine the best ways to communicate the importance for patients to access their medical information. We believe that with time patients will become more willing to use the technology to access their health records.

PROPOSED MODIFIED STAGE 2 OBJECTIVES AND MEASURES IN 2017 FOR ELIGIBLE HOSPITALS AND CAHS ATTESTING UNDER THE MEDICARE EHR INCENTIVE PROGRAM

Objective	Previous measure name/reference	Measure name	Threshold requirement
Protect Patient Health Information	Measure	Security Risk Analysis Measure	Yes/No attestation.
CDS (Clinical Decision Support) *	Measure 1	Clinical Decision Support Interventions Measure.	Five CDS.
	Measure 2	Drug Interaction and Drug-Allergy Checks Measure.	Yes/No.
CPOE (Computerized Provider Order Entry).*	Measure 1	Medication Orders Measure	>60%.
	Measure 2	Laboratory Orders Measure	>30%.
	Measure 3	Radiology Orders Measure	>30%.
eRx (electronic prescribing)	Measure	e-Prescribing	>10%.
Health Information Exchange	Measure	Health Information Exchange Measure.	>10%.
Patient Specific Education	Eligible Hospital/CAH Measure	Patient-Specific Education Measure.	>10%.
Medication Reconciliation	Measure	Medication Reconciliation Measure.	>50%.
Patient Electronic Access	Eligible Hospital/CAH Measure 1	Patient Access Measure	>50%.
	Eligible Hospital/CAH Measure 2	View Download Transmit (VDT) Measure.**	At least 1 patient.
Public Health Reporting	Immunization Reporting	Immunization Measure	Public Health Reporting to 3 Registries.
	Syndromic Surveillance Reporting	Syndromic Surveillance Measure.	
	Specialized Registry Reporting	Specialized Registry Measure.	
	Electronic Reportable Laboratory Result Reporting.	Electronic Reportable Laboratory Result Reporting Measure.	

* We note that we are proposing to remove CDS and CPOE for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program in section XVIII.C.1. of this proposed rule.

** We note that we are proposing to reduce the threshold for the VDT measure.

We are seeking public comments on the proposed changes.

b. Proposed Changes to the Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018

For EHR reporting periods in 2017 and 2018, we are proposing to modify a subset of the Stage 3 measure thresholds established in the 2015 EHR Incentive Programs Final Rule (80 FR 62829 through 62871) that are currently codified at 42 CFR 495.24, and these proposed modifications would apply to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. For the reasons stated above, these proposed modifications would not apply to eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. We also are proposing, beginning in 2017, in proposed 42 CFR 495.24(c) and (d), to update the measures for EPs, eligible hospitals and CAHs with a new naming convention to allow for easier reference to a given measure, and to align with the measure nomenclature proposed for the MIPS (see the table summarizing Proposed Stage 3 Objectives and Measures for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, below).

(1) Objective: Patient Electronic Access to Health Information (Proposed 42 CFR 495.24(c)(5))

Objective: The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Patient Access Measure: For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (APIs) in the provider's CEHRT.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator (or patient-authorized representatives) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the provider's CEHRT.
- Threshold: The resulting percentage must be more than 50 percent in order for a provider to meet this measure.
- Exclusion: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.
- Proposed Modification to the Patient Access Measure Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(5)(ii)(A), to reduce the threshold for the Patient Access measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 80 percent to more than 50 percent. In the 2015 EHR Incentive Programs Final Rule (80 FR 62846), we finalized that providers in Stage 3 would be required to offer all four functionalities (view, download, transmit and access through an API) to their patients.

We continue to hear from health IT vendors through correspondence regarding concerns about the implementation of APIs for Stage 3, indicating, in part that application development is in a fledgling state, and thus it might be very difficult for hospitals to be ready to achieve the 80 percent threshold by the time Stage 3 is required starting in January 2018. Additional concerns were stated by vendors through written correspondence to CMS that stated in part that API requirements outlined in the 2015 EHR Incentive Programs Final Rule could place an excessive burden on hospitals because application development has not been entirely market tested and widely accepted amongst the entire industry. They went on further to provide that it will likely be difficult for hospitals to achieve the threshold of 80 percent at the implementation of Stage 3. Vendors have also expressed concerns around the likely issues surrounding compatibility and varying API interface functionalities that could possibly hinder interoperability among certified EHR technology. We are proposing to reduce the threshold based on the concerns voiced by these vendors and believe the Modified Stage 2 threshold of more than 50 percent is reasonable.

Patient-Specific Education Measure: The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the EHR reporting period.
- Threshold: The resulting percentage must be more than 10 percent in order for a provider to meet this measure.
- Exclusions: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the Patient Specific Education Measure Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(5)(ii)(B), to reduce the threshold for the Patient-Specific Education measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 35 percent to more than 10 percent. We continue to receive written correspondences from hospitals and hospital associations expressing their concerns that the vast majority of patients ask for and are given patient education materials at the time of discharge, usually in print form. These stakeholders have indicated that they believe patients benefit from this information at the time of their interaction with the health care professionals in the inpatient or emergency department settings of the hospital. Requiring hospitals to make patient education materials available electronically, which would be accessed after the patient is discharged, requires hospitals to set up a process and workflow that these stakeholders describe as administratively burdensome and the benefit would be diminished for patients who have limited knowledge of, proficiency with or access to information technology or patients who request paper based educational resources.

(2) Objective: Coordination of Care Through Patient Engagement (Proposed 42 CFR 495.24(c)(6))

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

As finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62861), we maintain that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three measures to meet the Coordination of Care through Patient Engagement Objective.

View, Download, Transmit (VDT) Measure: During the EHR reporting period, at least one unique patient (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following: (1) View, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the EHR reporting period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the EHR reporting period.
- Threshold: The numerator must be at least one patient in order for an eligible hospital or CAH to meet this measure.
- Exclusion: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the View, Download, Transmit (VDT) Threshold

As discussed above, under the Modified Stage 2 Objectives and Measures, we are proposing to reduce the threshold of the View, Download Transmit (VDT) measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 5 percent to at least one patient. We are proposing, in proposed 42 CFR 495.24(c)(6)(ii)(A), to reduce the threshold for Stage 3 because we have heard from stakeholders including hospitals and hospital associations that they have faced significant challenges in implementing the objectives and measures that require patient action. These challenges include but are not limited to, patients who have limited knowledge of, proficiency with and access to information technology as well as patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform. We recognize that eligible hospitals and CAHs may need additional time to educate patients on how to use health information technology and believe that reducing the threshold for 2017 and 2018 would provide additional time for eligible hospitals and CAHs to determine the best ways to communicate the importance for patients to access their medical information. We believe with time patients will become more willing to use the technology to access their health records.

Secure Messaging: For more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

- Denominator: The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the EHR reporting period.
- Threshold: The resulting percentage must be more than 5 percent in order for an eligible hospital or CAH to meet this measure.
- Exclusion: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the Secure Messaging Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(6)(ii)(B), to reduce the threshold of the Secure Messaging measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 25 percent to more than 5 percent.

We are proposing to reduce the threshold because we have heard from stakeholders including hospitals and hospital associations that for patients who are in the hospital for an isolated incident the hospital may not have significant reason for a follow up secure message. In addition, we have heard concerns from these same stakeholders that these same patients may decline to access the messages received through this platform. They have expressed concern over not being able meet this threshold as a result of their patients' limited knowledge of, proficiency with, and access to information technology. We understand that hospitals have faced challenges meeting this measure. We believe the goal of this measure is to leverage HIT solutions to enhance patient and provider engagement. This type of platform is also meant to be of value for communication between multiple providers in the care team and patient which could promote care coordination and better outcomes for the patient. Therefore we would like to provide eligible hospitals and CAHs additional time to determine the best ways to relay the importance for patients to use secure messaging as a communication tool with their healthcare provider. We do believe that with time patients will become more willing to use secure messages as a means to communicate with their health care provider.

(3) Objective: Health Information Exchange (HIE) (Proposed 42 CFR 495.24(c)(7))

Objective: The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

As finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62861), we maintain that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three measures to meet the Health Information Exchange Objective.

Patient Care Record Exchange Measure: For more than 10 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- Denominator: Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.
- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.
- Threshold: The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.
- Exclusion: Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the Patient Care Record Exchange Measure for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(A), to reduce the threshold for the Patient Care Record Exchange measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 50 percent to more than 10 percent.

Hospital and hospital association feedback on the 2015 EHR Incentive Programs Final Rule, as well as recent reports and surveys of hospital participants show that there are still challenges to achieving wide scale interoperable health information exchange.[122] Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. For example, reports note that adoption of health IT may be less extensive among common hospital trading partners such as occupational and physical therapists, behavioral health providers, and long term post-acute care facilities. Stakeholders have emphasized that while the majority of hospitals are now engaging in health IT supported health information exchange, achieving high performance will require further saturation of these health IT supports throughout the industry. We believe the threshold of more than 10 percent for exchange of summary of care is reasonable, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened.

Request/Accept Patient Care Record Measure: For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

- Denominator: Number of patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

---

[122] ONC Data Brief: No. 36—May 2016 *https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf.*

- Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.
- Threshold: The percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.
- Exclusions:
  - Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.
  - Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
- Proposed Modification to the Request/Accept Patient Care Record Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(B), to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Request/Accept Patient Care Record Measure from more than 40 percent to more than 10 percent. Hospital and hospital association feedback on the 2015 EHR Incentive Programs Final Rule, as well as recent reports and surveys of hospital participants show that there are still challenges to achieving wide scale interoperable health information exchange.[123] Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. For example, reports note that adoption of health IT may be less extensive among common hospital trading partners such as occupational and physical therapists, behavioral health providers, and long term post-acute care facilities. Stakeholders have emphasized that while the majority of hospitals are now engaging in health IT supported health information exchange, achieving high performance will require further saturation of these health IT supports throughout the industry. We believe the threshold of more than 10 percent for request/accept patient care record measure is appropriate, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened.

Clinical Information Reconciliation Measure: For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known allergic medications; and (3) Current Problem list. Review of the patient's current and active diagnoses.

- Denominator: Number of transitions of care or referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.
- Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.
- Threshold: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.
- Exclusions: Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.
- Proposed Modification to the Clinical Information Reconciliation Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing, in proposed 42 CFR 495.24(c)(7)(ii)(C), to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Clinical Information Reconciliation Measure from more than 80 percent to more than 50 percent. As mentioned in both the Patient Care Record Exchange measure and the Request/Accept Patient Care Record measure, there are challenges to achieving wide scale interoperable health information exchange. Specifically, more than 50 percent of hospital stakeholders identified a lack of health IT adoption to support electronic exchange among trading partners as a key barrier, especially for provider types and settings of care where wide spread adoption may be slower. We believe the threshold of more than 50 percent for clinical information reconciliation is reasonable, and could likely be raised over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened. We will continue to review adoption and performance and consider increasing the threshold in future rulemaking.

(4) Objective: Public Health and Clinical Data Registry Reporting (Proposed 42 CFR 495.24(c)(8))

Objective: The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure (proposed 42 CFR 495.24(c)(8)(A))

Syndromic Surveillance Reporting Measure (proposed 42 CFR 495.24(c)(8)(B))

Electronic Case Reporting Measure (proposed 42 CFR 495.24(c)(8)(C))

Public Health Registry Reporting Measure (proposed 42 CFR 495.24(c)(8)(D))

Clinical Data Registry Reporting Measure (proposed 42 CFR 495.24(c)(8)(E))

Electronic Reportable Laboratory Result Reporting Measure (proposed 42 CFR 495.24(c)(8)(F))

- Proposed Modification to the Public Health and Clinical Data Registry Reporting Requirements for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

We are proposing to reduce the reporting requirement for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Public Health and Clinical Data Registry Reporting, in proposed 42 CFR 495.24(c)(8)(ii), to the Modified Stage 2 requirement of any combination of three measures from any combination of six measures in alignment with Modified Stage 2 requirements (80 FR 62870). We received written correspondence from hospitals and hospital associations indicating that it is often difficult to find registries that are able to accept data that will allow them successfully attest. Hospitals and hospital associations have indicated that it is administratively burdensome to seek out registries in their jurisdiction, contact the registries to determine if they are accepting data in the standards required, then determine if they meet the exclusion criteria if they are unable to send data to a registry. In addition, we have received written correspondence from hospitals indicating that in some instances additional technologies were required to transmit data, which prevented them from doing so. Because of these concerns, we believe that reducing the reporting requirements to any combination of three measures would still add value while minimizing the administrative burden.

---

[123] Ibid.

PROPOSED STAGE 3 OBJECTIVES AND MEASURES FOR 2017 AND 2018 FOR ELIGIBLE HOSPITALS AND CAHS ATTESTING UNDER THE MEDICARE EHR INCENTIVE PROGRAM

Objective	Previous measure name/reference	Measure name	Threshold requirement
Protect Patient Health Information	Measure	Security Risk Analysis Measure	Yes/No attestation.
eRx (electronic prescribing)	Eligible hospital/CAH Measure	e-Prescribing	>25%.
CDS (Clinical Decision Support) *	Measure 1	Clinical Decision Support Interventions Measure.	Five CDS.
	Measure 2	Drug Interaction and Drug-Allergy Checks Measure.	Yes/No.
CPOE (Computerized Provider Order Entry).*	Measure 1	Medication Orders Measure	>60%.
	Measure 2	Laboratory Orders Measure	>60%.
	Measure 3	Diagnostic Imaging Orders Measure.	>60%.
Patient Electronic Access to Health Information.	Measure 1	Patient Access Measure **	>50%.
	Measure 2	Patient-Specific Education Measure.**	>10%.
Coordination of Care through Patient Engagement.	Measure 1	View, Download Transmit (VDT) Measure.**	>At least 1 patient.
	Measure 2	Secure Messaging **	>5%.
	Measure 3	Patient Generated Health Data Measure.	>5%.
Health Information Exchange	Measure 1	Patient Care Record Exchange Measure.**	>10%.
	Measure 2	Request/Accept Patient Care Record Measure.**	>10%.
	Measure 3	Clinical Information Reconciliation Measure.**	>50%.
Public Health and Clinical Data Registry Reporting.	Immunization Registry Reporting Syndromic Surveillance Reporting Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting.	Immunization Registry Reporting Measure Syndromic Surveillance Reporting Measure Case Reporting Measure Public Health Registry Reporting Measure Clinical Data Registry Reporting Measure Electronic Reportable Laboratory Result Reporting Measure.	Report to 3 Registries or claim exclusions.

* We note that we are proposing to remove CDS and CPOE for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program in section XVIII.C.1. of this proposed rule. These objectives are included in the table to demonstrate what their measures and thresholds would be if we were not to finalize our proposal to remove them.

** We note that we are proposing to reduce the thresholds for these measures.

We are inviting public comments on our proposals. We also are seeking public comments on how measures of meaningful use under the EHR Incentive Program can be made more stringent in future years, consistent with the requirements of section 1886(n)(3)(A) of the Act. For example, we welcome comments on the proposed thresholds or whether different thresholds would be more appropriate. In addition, we are seeking public comments on new and more stringent measures for future years of the EHR Incentive Program. We will consider these comments for future enhancements of the EHR Incentive Program in future rulemaking. We intend to reevaluate the objectives, measures, and other program requirements for Stage 3 in 2019 and subsequent years. We note that our proposed revisions to the regulation text at 495.24 would only include objectives and measures for eligible hospitals and CAHs for Stage 3 in 2017 and 2018. We request comments on any changes that hospitals and other stakeholders believe should be made to the objectives and measures for Stage 3 in 2019 and subsequent years.

As stated in the previous sections, we are not proposing any changes to the objectives and measures for Modified Stage 2 for 2017 or Stage 3 for 2017 and 2018 for eligible hospitals and CAHs that attest under a State's Medicaid EHR Incentive Program. We considered proposing the same changes for both Medicare and Medicaid, but based upon our concerns that States would incur additional cost and time burdens in having to update their technology and reporting systems within a short period of time, we are proposing these changes only for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program. We request comments on whether these proposed changes should also apply for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program. Specifically, whether the proposed changes to eliminate the CPOE and CDS objectives and measures and reduce a subset of the measure thresholds for Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018 should also apply for eligible hospitals and CAHs that seek to qualify for an incentive payment for meaningful use under Medicaid. We request comments from State Medicaid agencies concerning our assumptions about the additional cost and time burdens they would face in accommodating these changes, and whether those burdens would exist for both 2017 and 2018.

D. Proposed Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs

1. Definition of "EHR Reporting Period" and "EHR Reporting Period for a Payment Adjustment Year"

In the 2015 EHR Incentive Programs Final Rule, we finalized the EHR reporting periods in 2015, 2016, 2017, 2018, and subsequent years for the incentive payments under Medicare and Medicaid (80 FR 62776 through 62781) and the downward payment adjustments under Medicare (80 FR 62904 through 62910), and made corresponding revisions to the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" under 42 CFR 495.4. For 2016, the EHR reporting period is any continuous 90-day period in CY 2016 for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) and the full CY 2016 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants). For the payment adjustments for EPs and eligible hospitals that are new participants, the EHR reporting period is any continuous 90-day period in CY 2016 and applies for the 2017 payment adjustment year and 2018 payment adjustment year; and for EPs and eligible hospitals that are returning participants, the EHR reporting period is the full CY 2016 and applies for the 2018 payment adjustment year. For the payment adjustments for CAHs that are new participants, the EHR reporting period is any continuous 90-day period in CY 2016 and applies for the 2016 payment adjustment year; and for CAHs that are returning participants, the EHR reporting period is the full CY 2016 and applies for the 2016 payment adjustment year. Certain attestation deadlines and other program requirements must be satisfied in order for an EP, eligible hospital, or CAH to avoid a payment adjustment for a particular year.

In the 2015 EHR Incentive Programs Final Rule (80 FR 62778 through 62779), we noted that many commenters overwhelmingly supported a 90-day EHR reporting period in 2015, while several commenters recommended a 90-day EHR reporting period for all providers in 2016 and subsequent years. In that rule, we explained a 90-day EHR reporting period in 2015 will allow providers additional time to address any remaining issues with the implementation of EHR technology certified to the 2014 Edition and to accommodate the proposed changes to the objectives and measures of meaningful use for 2015. We declined to extend the 90-day EHR reporting period beyond 2015 for returning participants because, in 2012 and 2013, thousands of returning providers successfully attested to program requirements for an EHR reporting period of one full calendar year and hardship exceptions may be available for providers experiencing extreme and uncontrollable circumstances.

Following the publication of the 2015 EHR Incentive Programs Final Rule, we received additional feedback from hospitals, hospital associations, eligible professionals and other clinical associations stating concerns regarding the finalized requirements. We now understand from those stakeholders that more time is needed to accommodate some of the updates from the 2015 EHR Incentive Programs Final Rule. These updates include, but are not limited to, system changes to the CEHRT, including implementation of an API which is a unique user interface that allows patients, through an application of their choice (including third-party applications), to pull certain components of their unique health data directly from the provider's CEHRT. We understand from hospitals and EHR vendors that APIs require a great deal of time to configure the software to accommodate such changes, including the user interface. We also received correspondence from eligible professionals expressing concern related to the requirements under MIPS and their transition to that program, and have shared interest in ensuring their readiness to report under the MIPS program in 2017. We believe this proposal is responsive to additional stakeholder feedback received through both correspondence and in-person meetings which requested that we allow a 90-day EHR reporting period in 2016 in order to reduce the reporting burden and increase flexibility in the program.

Therefore, we are proposing to change the EHR reporting periods in 2016 for returning participants from the full CY 2016 to any continuous 90-day period within CY 2016. This would mean that all EPs, eligible hospitals and CAHs may attest to meaningful use for an EHR reporting period of any continuous 90-day period from January 1, 2016 through December 31, 2016. The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2016, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking. We are proposing corresponding changes to the definition of "EHR reporting period" "and EHR reporting period for a payment adjustment year" at 42 CFR 495.4.

We are inviting public comments on our proposal.

2. Clinical Quality Measurement

In connection with our proposal to establish a 90-day EHR reporting period in 2016, and for the reasons discussed in the preceding section, we also are proposing a 90-day reporting period for clinical quality measures (CQMs) for all EPs, eligible hospitals, and CAHs that choose to report CQMs by attestation in 2016. We note that this proposal would have no impact on the requirements for CQM data that are electronically reported as established in prior rulemaking. In 2016, we are proposing that providers may:

- Report CQM data by attestation for any continuous 90-day period during calendar year 2016 through the Medicare EHR Incentive Program registration and attestation site; or
- Electronically report CQM data in accordance with the requirements established in prior rulemaking.

We note that, for EPs, eligible hospitals and CAHs, CQM data submitted via attestation can be submitted for a different 90-day period than the EHR reporting period for the meaningful use objectives and measures.

We are inviting public comment on our proposal.

E. Proposal To Require Modified Stage 2 for New Participants in 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62873), we outlined the requirements for EPs, eligible hospitals, and CAHs using CEHRT in 2017 as it relates to the objectives and measures they select to report. Specifically, we stated that:

- A provider that has technology certified to the 2015 Edition may attest to Stage 3 or to the Modified Stage 2 requirements.
- A provider that has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) The Modified Stage 2 requirements; or (2) potentially to the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.
- A provider that has technology certified to the 2014 Edition only may attest to the Modified Stage 2 requirements and may not attest to Stage 3.

After the publication of the 2015 EHR Incentive Programs Final Rule, we determined that, due to cost and time limitation concerns related specifically to 2015 Edition CEHRT updates in the EHR Incentive Program Registration and Attestation System, it is not technically feasible for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in 2017 in the EHR Incentive Program Registration and Attestation System. For this reason, we are proposing that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation system, or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation System, would be required to attest to the Modified Stage 2 objectives and measures. This proposal does not apply to EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants) attesting for an EHR reporting period in 2017. In early 2018, these returning eligible hospitals and CAHs will be transitioned to other reporting systems to attest for 2017, such as the Hospital IQR Program reporting portal. Eligible professionals who have successfully demonstrated meaningful use in a prior year would not be attesting under the Medicare EHR Incentive Program for 2017, because the applicable EHR reporting period for the 2018 payment adjustment is in 2016 (80 FR 62906), and 2016 is also the final year of the incentive payment under section 1848(o)(1)(A)(ii) of the Act.

We further note that providers using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

We are proposing corresponding revisions to the regulations at proposed 42 CFR 495.40(a)(2)(i)(F) and 42 CFR 495.40(b)(2)(i)(F) to require new participants to attest to the Modified Stage 2 objectives and measures for 2017.

We note that we also are proposing an editorial correction to the introductory language to 42 CFR 495.40(b), to correct the inadvertent omission of the word "satisfy" after the term "CAH must."

We are inviting public comments on our proposals.

F. Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017

In the September 4, 2012 Stage 2 final rule (77 FR 54093 through 54097), we finalized that eligible professionals (EPs) who have not successfully demonstrated meaningful use in a prior year (new participants) in the EHR Incentive Program may attest by October 1 to avoid a payment adjustment under section 1848(a)(7)(A) of the Act in the subsequent year. We note that these new participants are not necessarily newly enrolled in Medicare, but have been enrolled and have not previously attested to meaningful use for the EHR Incentive Program.

In the MIPS and APMs Proposed Rule (81 FR 28161 through 28586), we proposed calendar year 2017 as the first MIPS performance period. As established in the 2015 EHR Incentive Programs Final Rule (80 FR 62904 through 62908)), 2017 is also the last year in which new participants may attest to meaningful use (for a 90-day EHR reporting period in 2017) to avoid the 2018 payment adjustment. For example, an EP could use a 90-day reporting period from June through August 2017 to report under the Medicare EHR Incentive Program and, in the same time period, collect data for reporting under the Advancing Care Information performance category in MIPS. We understand that this overlap of reporting and performance periods in 2017 could be confusing to EPs who are new participants in the EHR Incentive Program and are also making the transition to MIPS because although both programs require the use of certified EHR technology, the measures and other requirements for meaningfully using that technology under the EHR Incentive Program are different from the measures and other requirements proposed under the advancing care information performance category of the MIPS. In addition, there are also different systems in which participants will have to register and attest. We also understand that these EPs, being new participants and likely new to EHR use and measurement, may be actively working with their vendors to build out their EHR technology and day-to-day EHR functions to align with the various and different requirements of the EHR Incentive Program and MIPS.

For these reasons, we are proposing to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment as authorized under section 1848(a)(7)(B) of the Act. We are limiting this proposal only to EPs who have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017 to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the advancing care information performance category under the MIPS in 2017. This proposed significant hardship exception is based upon our proposal in the MIPS and APMs Proposed Rule to establish 2017 as the first performance period of the MIPS. In the event we decide not to finalize that proposal, and instead adopt a different performance period for the MIPS that does not coincide with the final year for EPs to attest to meaningful use under the Medicare EHR Incentive Program, we may determine that this proposed significant hardship exception is not necessary.

To apply for this significant hardship exception, an EP would submit an application by October 1, 2017 (or a later date specified by CMS) to CMS that includes sufficient information to show that they are eligible to apply for this particular category of significant hardship exception. The application must also explain why, based on their particular circumstances, demonstrating meaningful use for the first time in 2017 under the EHR Incentive Program and also reporting on measures specified for the advancing care information performance category under the MIPS in 2017 would result in a significant hardship. EPs should retain all relevant documentation of this hardship for six years post attestation.

We believe this new category of significant hardship exception would allow the EPs who are new to certified EHR technology to focus on their transition to MIPS, and allow them to work with their EHR vendor to build out an EHR system focused on the goals of patient engagement and interoperability, which are important pillars of patient-centered care and expected to be highly emphasized under the MIPS APMs

Proposed Rule. It would also allow EPs to identify which objectives and measures are most meaningful to their practice which is a key feature of the proposed MIPS advancing care information performance category. We are also proposing to amend the regulations by adding new section 495.102(d)(4)(v) to include this new category of significant hardship exception.

We are inviting public comment on our proposal.

G. Proposed Modifications To Measure Calculations for Actions Outside the EHR Reporting Period

In the 2015 EHR Incentive Programs Final Rule (80 FR 62808), we referenced FAQ 8231(*https://questions.cms.gov/faq.php?isDept=0&search=8231&searchType=faqId&submitSearch=1&id=5005*) which states that for all meaningful use measures, unless otherwise specified, actions may fall outside the EHR reporting period timeframe but must take place no earlier than the start of the reporting year and no later than the date of attestation. We realize this open-ended timeframe could be confusing to providers and could vary widely among providers as their date of attestation could fall anywhere from January 1 through February 28 (or other date specified by CMS) after the year in which their EHR reporting period occurs. For these reasons, and to be consistent with incorporation of data from one EHR reporting period we are proposing that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. For example, if the EHR reporting period is any continuous 90-day period within CY 2017, the action must occur between January 1 and December 31, 2017, but does not have to occur within the 90-day EHR reporting period timeframe.

We note that FAQ 8231 was intended to help providers who initiate an action in their EHR after December 31 that is related to a patient encounter that occurred during the year of the EHR reporting period. We understand that a small number of actions may occur after December 31 of the year in which the EHR reporting period occurs. However, we believe that the reduced measure thresholds proposed in this proposed rule would significantly reduce the impact that these actions would have on performance. In addition, we note that actions occurring after December 31 of the reporting year would count toward the next calendar year's EHR reporting period.

We are inviting public comment on our proposal.

XIX. Proposed Additional Hospital Value-Based Purchasing (VBP) Program Policies

A. Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. We refer readers to the FY 2017 IPPS/LTCH PPS proposed rule for a full discussion of the Hospital VBP Program and its proposed policies (81 FR 25099 through 25117).

B. Proposed Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program

1. Background of the HCAHPS Survey in the Hospital VBP Program

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP Program measures, other than readmission measures, for purposes of the program. CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital VBP Program beginning with the FY 2013 program year (76 FR 26510), and we added the 3-Item Care Transition Measure (CTM–3) (NQF #0228) as the ninth dimension in the HCAHPS Survey beginning with the FY 2018 program year (80 FR 49551 through 49553). The HCAHPS Survey scores for the Hospital VBP Program are the basis for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

The HCAHPS Survey is the first national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey asks discharged patients 32 questions about their recent hospital stay. Survey results are used to score nine dimensions of the patient's experience of care for the Hospital VBP Program, as the table below illustrates.

HCAHPS SURVEY DIMENSIONS FOR THE FY 2018 PROGRAM YEAR

Communication with Nurses.
Communication with Doctors.
Responsiveness of Hospital Staff.
Pain Management.
Communication About Medicines.
Hospital Cleanliness & Quietness.
Discharge Information.
3-Item Care Transition.
Overall Rating of Hospital.

The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines, which is available on the official HCAHPS Web site at: *http://www.hcahpsonline.org/qaguidelines.aspx*. AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. In May 2005, the HCAHPS Survey was endorsed by the NQF.

2. Background of the Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain Performance Scoring Methodology

As finalized beginning with the FY 2018 program year (80 FR 49565 through 49566), for each of the 9 dimensions of the HCAHPS Survey that we have adopted for the Hospital VBP Program, we calculate Achievement Points (0 to 10 points) and Improvement Points (0 to 9 points), the larger of which is summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0 to 90 points). The prenormalized HCAHPS Base Score is then multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up; values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions is weighted equally, so that the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points are then calculated and range from 0 to 20 points. The Consistency Points consider scores across all nine of the dimensions. The final element of the scoring formula is the sum of the HCAHPS Base Score and the HCAHPS Consistency Points, and that sum will range from 0 to 100 points. The Patient- and Caregiver-Centered Experience of Care/Care Coordination domain accounts for 25 percent of a hospital's Total Performance Score (TPS) for the FY 2018 program year (80 FR 49561).

3. Proposed Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program Beginning With the FY 2018 Program Year

As noted above, one of the HCAHPS Survey dimensions that we have adopted for the Hospital VBP Program is Pain Management. Three survey questions are used to construct this dimension,[124] as follows:

- 12. During this hospital stay, did you need medicine for pain?

☐ Yes
☐ No (If No, Go to Question 15)

- 13. During this hospital stay, how often was your pain well controlled?

☐ Never
☐ Sometimes
☐ Usually
☐ Always

- 14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

☐ Never
☐ Sometimes
☐ Usually
☐ Always

We have received feedback that some stakeholders are concerned about the Pain Management dimension questions being used in a program where there is any link between scoring well on the questions and higher hospital payments. Some stakeholders believe that the linkage of the Pain Management dimension questions to the Hospital VBP Program payment incentives creates pressure on hospital staff to prescribe more opioids in order to achieve higher scores on this dimension. Many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Pain Management dimension and opioid prescribing practices, including misuse of the survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance) and failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis).

Because some hospitals have identified patient experience as a potential source of competitive advantage, we have heard that some hospitals may be disaggregating their raw HCAHPS data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. The HCAHPS Survey was never intended to be used in these ways.[125]

We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. It is important to note that the HCAHPS Survey does not specify any particular type of pain control method. In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. Although we are not aware of any scientific studies that support an association between scores on the Pain Management dimension questions and opioid prescribing practices, we are developing alternative questions for the Pain Management dimension in order to remove any potential ambiguity in the HCAHPS Survey. We are following our standard survey development processes, which include drafting alternative questions, cognitive interviews and focus group evaluation, field testing, statistical analysis, stakeholder input, the Paperwork Reduction Act, and NQF endorsement. HHS is also conducting further research to help better understand these stakeholder concerns and determine if there are any unintended consequences that link the Pain Management dimension questions to opioid prescribing practices. In addition, we are in the early stages of developing an electronically specified process measure for the inpatient and outpatient hospital settings that would measure concurrent prescribing of an opioid and benzodiazepine. We also are in the early stages of developing a process measure that would assess whether inpatient psychiatric facilities are regularly monitoring for adverse drug events of opioid and psychotropic drugs. The measure specifications will be posted on the CMS Web page and the public will have an opportunity to provide feedback before we make any proposal to adopt it for quality reporting purposes.

Due to some potential confusion about the appropriate use of the Pain Management dimension questions in the Hospital VBP Program and the public health concern about the ongoing prescription opioid overdose epidemic, while we await the results of our ongoing research and the above-mentioned modifications to the Pain Management dimension questions, we are proposing to remove the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain beginning with the FY 2018 program year. The FY 2018 program year uses HCAHPS performance period data from January 1, 2016 to December 31, 2016 to calculate each hospital's TPS, which affects FY 2018 payments. When modified Pain Management questions for the HCAHPS Survey become available for use in the Hospital VBP Program, we intend to propose to adopt them in future rulemaking.

If our proposal to remove the Pain Management dimension is finalized, this would leave eight dimensions in the HCAHPS Survey for use in the Hospital VBP Program, as the table below illustrates.

PROPOSED HCAHPS SURVEY DIMENSIONS FOR THE FY 2018 PROGRAM YEAR

Communication with Nurses.
Communication with Doctors.
Responsiveness of Hospital Staff.
Communication About Medicines.
Hospital Cleanliness & Quietness.
Discharge Information.
3-Item Care Transition.
Overall Rating of Hospital.

In order to adjust for the removal of the HCAHPS Pain Management dimension from the Hospital VBP Program, we are proposing to continue to assign Achievement Points (0 to 10 points) and Improvement Points (0 to 9 points) to each of the remaining eight dimensions in order to create the HCAHPS Base Score (0 to 80 points). Each of the remaining eight dimensions would be of equal weight, so that the

---

[124] Available at: *http://www.hcahpsonline.org/surveyinstrument.aspx.*

[125] L. Tefera, W.G. Lehrman, and P. Conway. "Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches." *Journal of the American Medical Association.* Published online, 3–10–16. *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated, and would range from 0 to 20 points. The Consistency Points would consider scores across the remaining eight dimensions, and would not include the Pain Management dimension. The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and would range from 0 to 100 points.

For the FY 2018 program year, we finalized performance standards for the HCAHPS measures in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49566). In this proposed rule, we are proposing to remove the Pain Management dimension of the HCAHPS Survey in the calculation of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain score beginning with the FY 2018 program year. The performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

Proposed Performance Standards for the FY 2018 Program Year

HCAHPS survey dimension	Floor * (percent)	Achievement threshold ** (percent)	Benchmark *** (percent)
Communication with Nurses	55.27	78.52	86.68
Communication with Doctors	57.39	80.44	88.51
Responsiveness of Hospital Staff	38.40	65.08	80.35
Pain Management	N/A	N/A	N/A
Communication about Medicines	43.43	63.37	73.66
Hospital Cleanliness & Quietness	40.05	65.60	79.00
Discharge Information	62.25	86.60	91.63
3-Item Care Transition	25.21	51.45	62.44
Overall Rating of Hospital	37.67	70.23	84.58

* Floor is defined as the 0th percentile of the baseline (76 FR 26519).
** Achievement threshold is defined as the 50th percentile of hospital performance in the baseline period (76 FR 26519).
*** Benchmark is defined as the mean of the top decile of hospital performance on each dimension (76 FR 26517).

For the FY 2019 program year, we proposed performance standards in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25114). We are proposing to remove the Pain Management dimension of the HCAHPS Survey in the calculation of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain score beginning with the FY 2018 program year. (In section IV.H.3.b. of that proposed rule, we also proposed to change the name of this domain to Person and Community Engagement domain beginning with the FY 2019 program year (81 FR 25100 through 25101).) The proposed performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

Proposed Performance Standards for the FY 2019 Program Year

HCAHPS survey dimension	Floor * (percent)	Achievement threshold ** (percent)	Benchmark *** (percent)
Communication with Nurses	16.32	78.59	86.81
Communication with Doctors	22.56	80.33	88.55
Responsiveness of Hospital Staff	21.91	65.00	80.27
Pain Management	N/A	N/A	N/A
Communication about Medicines	6.19	63.18	73.51
Hospital Cleanliness & Quietness	13.78	65.64	79.12
Discharge Information	60.58	86.88	91.73
3-Item Care Transition	4.26	51.35	62.73
Overall Rating of Hospital	30.52	70.58	84.68

* Floor is defined as the 0th percentile of the baseline (76 FR 26519).
** Achievement threshold is defined as the 50th percentile of hospital performance in the baseline period (76 FR 26519).
*** Benchmark is defined as the mean of the top decile of hospital performance on each dimension (76 FR 26517).

We are inviting public comments on these proposals.

XXI. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this proposed rule pertaining to proposed CY 2017 payments under the OPPS, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select "1656–P" from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled "Proposed 2017 OPPS 1656–P Addenda" at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed CY 2017 payments under the ASC payment system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select "1656–P" from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled "Addendum AA, BB, DD1, DD2, and EE".

XXII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

B. ICRs for the Hospital OQR Program

1. Background

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program (76 FR 74451). We refer readers to the CY 2011 through CY 2016 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; and 80 FR 70580 through 70582, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109.

Below we discuss only the changes in burden resulting from the provisions in this proposed rule.

2. Estimated Burden of Hospital OQR Program Proposals for the CY 2018 Payment Determination and Subsequent Years

In section XIII.B.8. of this proposed rule, we are proposing to publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that hospitals will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We do not anticipate additional burden to hospitals as a result of these proposed changes to the public display policies because hospitals would not be required to submit additional data or forms to CMS.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2019 Payment Determination and Subsequent Years

a. Extraordinary Circumstances Extension or Exemptions Process

In section XIII.D.8. of this proposed rule, we are proposing to extend the submission deadline for requests under our "Extraordinary Circumstances Extension or Exemptions" (ECE) process from 45 days from the date that the extraordinary circumstance occurred to 90 days from the date that the extraordinary circumstance occurred. For a complete discussion of our ECE process under the Hospital OQR Program, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524).

We believe that the proposed updates to the ECE deadlines will have no effect on burden for hospitals, because we are not making any changes that will increase the amount of time necessary to complete the form. We do not anticipate that there would be any additional burden as the materials to be submitted related to an ECE request are unchanged and the deadline does not result in a change in time to submit an extension or exemption request. The burden associated with submitting an Extraordinary Circumstances Extension/Exemption Request is accounted for in OMB Control Number 0938–1022.

b. Reconsideration and Appeals

In section XIII.D.9. of this proposed rule, we are proposing a clarification to our reconsideration and appeals procedures. While there is a burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of administrative actions such as reconsiderations.

4. Estimated Burden of Hospital OQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

In sections XIII.B.5.a. and XIII.B.5.b. of this proposed rule, we are proposing two new claims-based measures for the CY 2020 payment determination and subsequent years: (1) OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and (2) OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). In section XIII.B.5.c. of this proposed rule, we also are proposing five new Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures for the CY 2020 payment determination and subsequent years: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility.

The data used to calculate scores on the proposed OP–35 or OP–36 measures are derived from Medicare FFS claims. As noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate the claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. As a result, we do not anticipate that the proposed OP–35 or OP–36 measures would create any additional burden to hospital outpatient departments for the CY 2020 payment determination and subsequent years.

The information collection requirements associated with the five OAS CAHPS Survey-based measures (proposed OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB Control Number 0938–1240. For this reason, we are not providing an independent estimate of the burden associated with OAS CAHPS Survey-based measures for the Hospital OQR Program. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70580 through 70582) for burden information already discussed.

We are inviting public comment on the burden associated with these proposed information collection requirements.

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015 and CY 2016 OPPS/ASC final rules with comment periods (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; and 80 FR 70582 through 70584, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270.

Below we discuss only the changes in burden that would result from the provisions in this proposed rule.

2. Proposed Changes in Burden Calculation for the ASCQR Program

To better align this program with our other quality reporting and value-based purchasing programs, we are proposing to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are proposing to utilize: (1) A standard estimate of the time required for abstracting chart data for measures based on historical data from other quality reporting programs; and (2) a standard hourly labor cost for chart abstraction activities.

a. Estimate of Time Required to Chart-Abstract Data

In the past, we have used 35 minutes as the time required to chart-abstract and report data for each chart-abstracted Web-based measure in the ASCQR Program (76 FR 74554). However, we have studied other programs' estimates for this purpose and believe that 15 minutes is a more reasonable number. Specifically, the Hospital IQR Program possesses historical data from its data validation contractor. This contractor chart-abstracts each measure set when charts are sent to CMS for validation. Based on this contractor's validation activities, we believe that the average time required to chart-abstract data for each measure is approximately 15 minutes. We believe that this estimate is reasonable because the ASCQR Program uses measures similar to those of the Hospital IQR Program, such as the surgery safety measures and immunization measures. Accordingly, we are proposing to use 15 minutes in calculating the time required to chart-abstract data, unless we have historical data that indicate that this approximation is not accurate.

b. Hourly Labor Cost

Previously, we used $30 as our hourly labor cost in calculating the burden associated with chart-abstraction activities. This labor cost is different from those used in other quality reporting and value-based purchasing programs, and we do not believe there is a justification for these different numbers given the similarity in quality measures and required staff. Therefore, we are proposing to align these numbers and use one hourly labor cost across programs for purposes of burden calculations. Specifically, we are proposing to use an hourly labor cost (hourly wage plus fringe and overhead, as discussed below) of $32.84. This labor cost is based on the BLS wage for a Medical Records and Health Information Technician. The BLS is "the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy." [126] Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data. Therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for these measures. According to the BLS, the median pay for Medical Records and Health Information Technicians is $16.42 per hour.[127]

However, obtaining data on other overhead costs is challenging because overhead costs may vary greatly across ASCs. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the facility level. Therefore, we are proposing to calculate the cost over overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. We note that in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25251 through 25152, 25256, and 25319) we are using a similar adjustment for several other quality reporting programs. Therefore, we are proposing to apply an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe and overhead) to our burden calculations.

3. Estimated Burden of ASCQR Program Proposals for the CY 2018 Payment Determination

For the CY 2018 payment determination and subsequent years, we are making one new proposal. In section XIV.B.7 of this proposed rule, we are proposing publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that ASCs will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We believe that these proposed changes to the ASCQR Program public reporting policies will have no effect on burden for ASCs because these changes would not require participating ASCs to submit additional data to CMS.

4. Estimated Burden of ASCQR Program Proposals for the CY 2019 Payment Determination

For the CY 2019 payment determination and subsequent years, we are making two new proposals. In section XIV.D.3. of this proposed rule, we are proposing to implement a submission deadline with an end date of May 15 for all data submitted via a Web-based tool (CMS or non-CMS) beginning with the CY 2019 payment determination. We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline would be moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. We also are proposing to make corresponding changes to the regulations at 42 CFR 416.310(c)(1)(ii). We do not anticipate any additional burden to ASCs as a result of codifying this policy.

In addition, in section XIV.D.6. of this proposed rule, we are proposing to extend the time for filing an Extraordinary Circumstance Exception or Exemption from within 45 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred. We do not anticipate that there would be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit an extension or exemption. We also are proposing to make corresponding changes to the regulations at 42 CFR 416.310(d)(1). We do not anticipate any additional burden to ASCs as a result of codifying this policy.

---

[126] *http://www.bls.gov/bls/infohome.htm.*

[127] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

5. Estimated Burden of ASCQR Program Proposals for the CY 2020 Payment Determination

For the CY 2020 payment determination and subsequent years, we are proposing to add two new measures collected via a CMS online data submission tool and five survey-based measures to the ASCQR Program measure set. In section XIV.B.4. of this proposed rule, we are proposing the following measures collected via a CMS online data submission tool: ASC–13: Normothermia Outcome and ASC–14: Unplanned Anterior Vitrectomy. In the same section, we are proposing to adopt the following survey-based measures: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility.

We believe ASCs would incur a financial burden associated with abstracting numerators, denominators, and exclusions for the two proposed measures collected and reported via a CMS online data submission tool (proposed ASC–13 and ASC–14). Using the proposed burden estimate values for chart-abstracted measures discussed in section XXI.C.2. of this proposed rule, we estimate that each participating ASC would spend 15 minutes per case to collect and submit the data, making the total estimated burden for all ASCs with a single case per ASC of 1,315 hours (5,260 ASCs × 0.25 hours per case per ASC), and 82,845 hours for each measure across all ASCS based on a historic average of 63 cases. Therefore, we estimate that the reporting burden for all ASCs with a single case per ASC for proposed ASC–13 and ASC–14 would be 1,315 hours and $42,185 (1,315 hours × $32.84 per hour), and 82,845 hours (1,315 × 63 cases) and $2,720,630 (82,845 hours × $32.84 per hour) for each measure across all ASCs based on an historic average of 63 cases for the CY 2020 payment determination. The additional burden associated with these requirements is available for review and comment under OMB Control Number 0938–1270.

The information collection requirements associated with the five proposed OAS CAHPS Survey-based measures (proposed ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB Control Number 0938–1240. For this reason, we are not providing an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582 through 70584) for burden information already discussed.

6. Reconsideration

For a complete discussion of the ASCQR Program's reconsideration processes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141), and the CY 2016 final rule with comment period (80 FR 75141). We are not proposing to make any changes to this process.

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of OMB's implementing regulations for the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of administrative actions such as reconsiderations.

We are inviting public comment on the burden associated with these information collection requirements.

D. ICRs Relating to Proposed Changes in Transplant Enforcement Performance Thresholds

In section XV. of this proposed rule, we discuss proposed changes to the enforcement performance thresholds relating to patient and graft survival outcomes. The proposed revisions would impose no new burdens on transplant programs. These proposals do not impose any new information collection or recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

E. ICRs for Proposed Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this proposed rule, we are proposing several changes to definitions, outcome measures and documentation requirements for OPOs. In section XVI.B.1. of this proposed rule, we are proposing a revision to the definition of "eligible death." In section XVI.B.2 of this proposed rule, we are proposing to adjust the outcome performance yield measure to align CMS with the SRTR yield metric. In section XVI.B.3. of this proposed rule, we are proposing to reduce the amount of hard copy documentation that is packaged and shipped with each organ. These proposals do not impose any new information collection or recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

Finally, in section XVII. of this proposed rule, we are proposing to make a technical correction to the enforcement provisions for transplant centers and to clarify our policy regarding SIAs. These proposals do not impose information collection and recordkeeping requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

F. ICRs Relating to Proposed Changes to the Electronic Health Record (EHR) Incentive Program

In section XVIII. of this proposed rule, we discuss our proposals for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Modified Stage 2 and Stage 3 to: Eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures; and reduce the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. We believe that there will be a reduction in burden by not reporting for the CDS (1 minute) and CPOE (10 minutes) objectives and measures. This would reduce the total burden associated with these measures by a total of 11 minutes. This would reduce the time to attest to objectives and measures for Modified Stage 2 (495.22) from 6 hours and 48 minutes to 6 hours and 37 minutes and for the Stage 3 from 6 hours and 52 minutes to 6 hours and 41 minutes. We refer readers to the 2015 EHR Incentive Programs Final Rule for the detailed analysis of the burden associated with the objectives and measures (80 FR 62916 through 62924).

While we do believe that eliminating requirements would decrease the associated information collection burden, we believe that the reduction detailed below falls within an acceptable margin of error and therefore we will not be revising the information collection request currently approved under 0938–1158.

We discuss our proposals to change the EHR reporting period in 2016 from the full CY 2016 to any continuous 90-day period within CY 2016 for all returning EPs, eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs; require new participants in 2017 who are seeking to avoid the 2018 payment adjustment by attestation by October 1, 2017 to the Modified Stage 2 objectives and measures. We do not believe that modifying the EHR reporting period would cause an increase in burden as the reporting requirements for a 90 day reporting period are the same for a full calendar year reporting period. Instead, the burden is associated with data capture and measure calculations on the objectives and measures not the reporting period to which one will attest for.

We discuss our proposals to allow for a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017. The hardship exception process involves participants completing an application form for an exception. While the form is standardized, we believe it is exempt from the PRA. The form is structured as an attestation. Therefore, we believe it is exempt under 5 CFR 1320.3(h)(1) of the implementing regulations of the PRA. The form is an attestation that imposes no burden beyond what is required to provide identifying information and to attest to the applicable information.

G. ICRs Relating to Proposed Additional Hospital VBP Program Policies

In section XIX. of this proposed rule, we discuss proposed changes in the requirements for the Hospital VBP Program. Specifically, we are proposing to change the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain by removing the HCAHPS Pain Management dimension. As required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is used in the Hospital IQR Program. Therefore, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. The proposed change to the scoring methodology for the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain in the Hospital VBP Program also would not result in any additional reporting burden.

H. ICRs for Payment for Off-Campus Provider-Based Departments Proposals for CY 2017

In section X.A. of this proposed rule, we discuss proposals for the implementation of section 603 of the Bipartisan Budget Act of 2015. The proposals would impose no new burdens on hospitals or providers. These proposals do not impose any new information collection or recordkeeping requirements for CY 2017. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 is not required.

We are inviting public comments on the burden associated with these information collection requirements.

XXIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing for CY 2017.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We are soliciting comments on the regulatory impact analysis in this proposed rule, and we will address the public comments we receive in the final rule with comment period as appropriate.

2. Statement of Need

This proposed rule is necessary to propose updates to the Medicare hospital OPPS rates. It is necessary to make proposed changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2017. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2015, through and including December 31, 2015, and processed through December 31, 2015, and updated cost report information.

This proposed rule also is necessary to propose updates to the ASC payment rates for CY 2017, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2017. Because ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the Proposed OPPS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2017 compared to CY 2016 due to the proposed changes in this proposed rule, would be approximately $671 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2017 would be approximately $5.1 billion higher relative to expenditures in CY 2016. We note that this estimate of $5.1 billion does not include the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 in CY 2017, which we estimate would reduce OPPS expenditures by $500 million in CY 2017. Because this proposed rule is economically significant as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 30 displays the distributional impact of the proposed CY 2017 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2016) would increase total OPPS payments by 1.6 percent in CY 2017. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2016 and CY 2017, considering all payments, proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 1.6 percent.

We estimate the proposed total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2017 compared to CY 2016 to be approximately $214 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Table 31 and Table 32 of this proposed rule display the redistributive impact of the proposed CY 2017 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2017 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2017 with the other supporting documentation for this proposed rule. To view the proposed hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select "regulations and notices" from the left side of the page and then select "CMS–1656–P" from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 30 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other proposed payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters. We are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 30 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 30, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2017, we are proposing to pay CMHCs for partial hospitalization services under only one proposed APC 5853 (Partial Hospitalization for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under only one proposed APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the proposed total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2017 is 2.8 percent (81 FR 25077). Section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.5 percentage point for FY 2017 (which is also the proposed MFP adjustment for FY 2017 in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the proposed OPD fee schedule increase factor of 1.55 percent. We are using the proposed OPD fee schedule increase factor of 1.55 percent in the calculation of the CY 2017 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2017 estimates in Table 30.

To illustrate the impact of the proposed CY 2017 changes, our analysis begins with a baseline simulation model that uses the CY 2016 relative payment weights, the FY 2016 final IPPS wage indexes that include reclassifications, and the final CY 2016 conversion factor. Table 30 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2017 over CY 2016 payments to hospitals and CMHCs as a result of the following factors: the impact of the proposed APC reconfiguration and recalibration changes between CY 2016 and CY 2017 (Column 2); the proposed wage indexes and the proposed provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.55 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all proposed payments for CY 2017 relative to all payments for CY 2016, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2017. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of proposed projected pass-through payment for CY 2017 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the proposed wage index changes on the hospital. However, proposed total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2016 and CY 2017 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2017 would increase Medicare OPPS payments by an estimated 1.6 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in a proposed estimated 1.7 percent increase in Medicare payments to all other hospitals. These proposed estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 30 shows the total number of facilities (3,862), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2015 hospital outpatient and CMHC claims data to model CY 2016 and proposed CY 2017 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2016 or proposed CY 2017 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals that are not also paid under the IPPS, since DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,747), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 49 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.2 percent to a decrease of 0.3 percent, depending on the number of beds. Rural hospitals would experience a 0.4 percent increase, with the impact ranging from an increase of 0.6 percent to no change, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.3 percent overall.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed fiscal year (FY) 2017 IPPS post-reclassification wage indexes; and the proposed rural adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2016 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of proposed budget neutrality for the proposed rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a proposed budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2017, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2017 scaled weights and a CY 2016 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2016 and CY 2017. The proposed FY 2017 wage policy results in modest redistributions.

There is no difference in impact between the CY 2016 cancer hospital payment adjustment and the proposed CY 2017 cancer hospital payment adjustment because we are proposing to use the same payment-to-cost ratio target in CY 2017 as in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363).

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 1.55 percent. Overall, these proposed changes would increase payments to urban hospitals by 1.5 percent and to rural hospitals by 2.3 percent. Most classes of hospitals would receive an increase in line with the proposed 1.6 percent overall increase after the proposed update is applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2017

Column 5 depicts the full impact of the proposed CY 2017 policies on each hospital group by including the effect of all of the proposed changes for CY 2017 and comparing them to all estimated payments in CY 2016. Column 5 shows the combined budget neutral effects of Column 2 and 3; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the difference in proposed total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2016 update (and assumed, for modeling purposes, to be the same number for CY 2017), we included 48 hospitals in our model because they had both CY 2015 claims data and recent cost report data. We estimate that the cumulative effect of all of the proposed changes for CY 2017 would increase payments to all facilities by 1.6 percent for CY 2017. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2016 and the proposed relative payment weights for CY 2017. We used the final conversion factor for CY 2016 of $73.725 and the proposed CY 2017 conversion factor of $74.909 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270) of 4.4 percent (1.0440) to increase individual costs on the CY 2015 claims, and we used the most recent overall CCR in the April 2016 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2016. Using the CY 2015 claims and a proposed 4.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2016, using a multiple threshold of 1.75 and a fixed-dollar threshold of $3,250 would be approximately 0.96 percent of total payments. The estimated current outlier payments of 0.96 percent are incorporated in the comparison in Column 5. We used the same set of claims and a proposed charge inflation factor of 9.0 percent (1.0898) and the CCRs in the April 2016 OPSF, with an adjustment of 0.9696, to reflect relative changes in cost and charge inflation between CY 2015 and CY 2017, to model the proposed CY 2017 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $3,825. The charge inflation and CCR inflation factors are discussed in detail in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25270 through 25273).

Overall, we estimate that facilities would experience an increase of 1.6 percent under this proposed rule in CY 2017 relative to total spending in CY 2016. This projected increase (shown in Column 5) of Table 30 reflects the proposed 1.55 percent OPD fee schedule increase factor, plus 0.03 percent to account for our proposal to package unrelated laboratory tests into OPPS payment, plus 0.02 percent for the proposed change in the pass-through estimate between CY 2016 and CY 2017, plus 0.04 percent for the difference in estimated outlier payments between CY 2016 (0.96 percent) and CY 2017 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2017 would increase payments to urban hospitals by 1.6 percent. Overall, we estimate that rural hospitals would experience a 2.3 percent increase as a result of the combined effects of all of the proposed changes for CY 2017.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 1.2 percent for major teaching hospitals and an increase of 1.9 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 1.7 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.7 percent, proprietary hospitals would experience an increase of 1.6 percent, and governmental hospitals would experience an increase of 1.5 percent.

TABLE 30—ESTIMATED IMPACT OF THE PROPOSED CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals (1)	APC recalibration (all proposed changes) (2)	New wage index and rovider adjustments (3)	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update (4)	All proposed changes (5)
ALL FACILITIES *	3,862	0.0	0.0	1.6	1.6
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,747	0.0	0.0	1.6	1.7
URBAN HOSPITALS	2,917	0.0	0.0	1.5	1.6
LARGE URBAN (GT 1 MILL.)	1,609	−0.1	−0.1	1.4	1.4
OTHER URBAN (LE 1 MILL.)	1,308	0.0	0.1	1.7	1.7
RURAL HOSPITALS	830	0.4	0.3	2.3	2.3
SOLE COMMUNITY	378	0.4	0.4	2.4	2.3
OTHER RURAL	452	0.4	0.3	2.2	2.2
BEDS (URBAN):					
0—99 BEDS	....	0.0	0.2	1.8	1.9
100–199 BEDS	827	0.2	−0.1	1.6	1.6
200–299 BEDS	463	0.1	−0.1	1.6	1.7
300–499 BEDS	403	0.0	0.0	1.6	1.6
500 + BEDS	214	−0.3	−0.1	1.2	1.3
BEDS (RURAL):					
0–49 BEDS	330	0.4	0.4	2.4	2.3
50–100 BEDS	304	0.6	0.4	2.5	2.5
101–149 BEDS	111	0.5	0.1	2.2	2.1
150–199 BEDS	47	0.2	0.5	2.4	2.3
200 + BEDS	38	0.0	0.3	2.0	2.0
REGION (URBAN):					
NEW ENGLAND	147	0.0	−1.1	0.5	0.5
MIDDLE ATLANTIC	348	0.0	−0.4	1.1	1.1
SOUTH ATLANTIC	460	0.0	0.0	1.7	1.7
EAST NORTH CENT	467	0.0	0.3	1.9	2.0
EAST SOUTH CENT	175	−0.3	0.2	1.5	1.6
WEST NORTH CENT	178	−0.1	0.2	1.6	1.5
WEST SOUTH CENT	512	−0.4	0.5	1.7	1.8
MOUNTAIN	203	0.2	−0.1	1.7	1.8
PACIFIC	377	0.3	−0.3	1.6	1.7
PUERTO RICO	50	−0.2	−0.2	1.2	1.2
REGION (RURAL):					
NEW ENGLAND	21	1.0	0.4	3.0	2.9
MIDDLE ATLANTIC	56	0.1	1.1	2.9	2.5
SOUTH ATLANTIC	125	0.3	−0.1	1.8	1.8
EAST NORTH CENT	121	0.5	0.5	2.6	2.6
EAST SOUTH CENT	158	0.2	0.1	1.9	2.0
WEST NORTH CENT	100	0.4	0.5	2.5	2.4
WEST SOUTH CENT	167	0.2	0.8	2.6	2.6
MOUNTAIN	58	0.6	−0.4	1.8	1.6
PACIFIC	24	0.6	−0.3	1.9	1.9
TEACHING STATUS:					
NON–TEACHING	2,691	0.2	0.1	1.9	1.9
MINOR	719	0.1	0.1	1.8	1.7
MAJOR	337	−0.3	−0.2	1.1	1.2
DSH PATIENT PERCENT:					
0	15	−2.2	0.1	−0.5	0.7
GT 0–0.10	311	−0.2	−0.1	1.2	1.3
0.10–0.16	275	0.2	0.0	1.8	1.8
0.16–0.23	602	0.2	0.1	1.9	1.9
0.23–0.35	1,148	0.1	0.1	1.7	1.7
GE 0.35	858	0.0	−0.1	1.5	1.5
DSH NOT AVAILABLE **	538	−3.7	−0.1	−2.3	−2.2
URBAN TEACHING/DSH:					
TEACHING & DSH	962	−0.1	−0.1	1.4	1.4
NO TEACHING/DSH	1,426	0.2	0.0	1.8	1.8
NO TEACHING/NO DSH	15	−2.2	0.1	−0.5	0.7
DSH NOT AVAILABLE**	514	−3.3	−0.2	−1.9	−1.9
TYPE OF OWNERSHIP:					
VOLUNTARY	1,981	0.1	0.0	1.7	1.7
PROPRIETARY	1,259	−0.1	0.0	1.5	1.6
GOVERNMENT	507	0.0	−0.1	1.4	1.5

TABLE 30—ESTIMATED IMPACT OF THE PROPOSED CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals (1)	APC recalibration (all proposed changes) (2)	New wage index and rovider adjustments (3)	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update (4)	All proposed changes (5)
CMHCs	49	−9.7	−0.2	−8.5	−8.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2017 OPPS policies and compares those to the CY 2016 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.000 because the payment-to-cost ratio target remains the same as in the CY 2016 OPPS/ASC final rule (80 FR 70362 through 70364).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.55 percent OPD fee schedule update factor (2.8 percent reduced by 0.5 percentage points for the proposed productivity adjustment and further reduced by 0.75 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying the frontier State wage adjustment.

* These 3,862 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 30 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2016, CMHCs are paid under two APCs for these services: APC 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) and APC 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs). For CY 2017, we are proposing to combine APCs 5851 and 5852 into proposed new APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this proposed APC policy assuming that CMHCs would continue to provide the same number of days of PHP care as seen in the CY 2015 claims data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs would experience an overall 8.4 percent decrease in payments from CY 2016 (shown in Column 5). We note that this would include the proposed trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2017 wage index values would result in a small decrease of 0.2 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2017 and the proposed FY 2017 wage index updates, would result in an estimated decrease of 8.5 percent. Column 5 shows that adding the proposed changes in outlier and pass-though payments would result in a total 8.4 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2017.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.5 percent for all services paid under the OPPS in CY 2017. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2017 comprehensive APC payment policy discussed in section II.A.2.e. of this proposed rule.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $671 million in program payments for OPPS services furnished in CY 2017. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XX.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

b. Estimated Effects of Proposed CY 2017 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2017 ASC relative payment weights by scaling the proposed CY 2017 OPPS relative payment weights by the ASC scalar of 0.9030. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 31 and 32 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2017 payment determinations will be based on the application of a 2.0 percentage points reduction to the annual update factor, which currently is the CPI–U. We calculated the proposed CY 2017 ASC conversion factor by adjusting the CY 2016 ASC conversion factor by 0.9992 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2016 and CY 2017 and by applying the proposed CY 2017 MFP-adjusted CPI–U update factor of 1.2 percent (projected CPI–U update of 1.7 percent minus a proposed projected productivity adjustment of 0.5 percentage point). The proposed CY 2017 ASC conversion factor is $44.684.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2017 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2015 and CY 2017 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2017 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of Proposed ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2017 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2017 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2015 claims data. Table 31 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2016 payments to estimated proposed CY 2017 payments, and Table 32 shows a comparison of estimated CY 2016 payments to estimated proposed CY 2017 payments for procedures that we estimate would receive the most Medicare payment in CY 2016.

Table 31 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 31.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2016 ASC Payments were calculated using CY 2015 ASC utilization (the most recent full year of ASC utilization) and CY 2016 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2016 ASC payments.
- Column 3—Estimated Proposed CY 2017 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to proposed updates to ASC payment rates for CY 2017 compared to CY 2016.

As seen in Table 31, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2017 would result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 1-percent decrease in aggregate payment amounts for digestive system procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, a 6-percent increase in aggregate payment amounts for musculoskeletal system procedures, no change in aggregate payment amounts for genitourinary system procedures, and a 2-percent decrease in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 31 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would be $32 million for CY 2017.

TABLE 31—ESTIMATED IMPACT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED CY 2017 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2016 ASC payments (in millions) (2)	Estimated proposed CY 2017 percent change (3)
Total	$4,020	2%
Eye and ocular adnexa	1,567	1
Digestive system	819	−1
Nervous system	692	3
Musculoskeletal system	469	6
Genitourinary system	180	0
Integumentary system	133	−2

Table 32 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2017. The table displays 30 of the procedures receiving the greatest estimated CY 2016 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2016 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2016 ASC Payments were calculated using CY 2015 ASC utilization (the most recent full year of ASC utilization) and the CY 2016 ASC payment rates. The estimated CY 2016 payments are expressed in millions of dollars.
- Column 4—Estimated Proposed CY 2017 Percent Change reflects the percent differences between the estimated ASC payment for CY 2016 and the estimated proposed payment for CY 2017 based on the proposed update.

TABLE 32—ESTIMATED IMPACT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2016 ASC payment (in millions) (3)	Estimated CY 2017 percent change (4)
66984	Cataract surg w/iol 1 stage	$1,115	−1
43239	Egd biopsy single/multiple	187	−13
45380	Colonoscopy and biopsy	181	12
45385	Colonoscopy w/lesion removal	119	12
66982	Cataract surgery complex	97	−1
64483	Inj foramen epidural l/s	87	18
63685	Insrt/redo spine n generator	82	2
64493	Inj paravert f jnt l/s 1 lev	71	−16
63650	Implant neuroelectrodes	66	14
66821	After cataract laser surgery	65	3
64635	Destroy lumb/sac facet jnt	55	1
29827	Arthroscop rotator cuff repr	54	9
G0105	Colorectal scrn; hi risk ind	54	−12
45378	Diagnostic colonoscopy	53	−14
G0121	Colon ca scrn not hi rsk ind	51	−12
0191T	Insert ant segment drain int	42	43
64590	Insrt/redo pn/gastr stimul	38	5
64721	Carpal tunnel surgery	33	1
29881	Knee arthroscopy/surgery	32	−9
15823	Revision of upper eyelid	32	−3
29880	Knee arthroscopy/surgery	28	−9
26055	Incise finger tendon sheath	25	−14
43235	Egd diagnostic brush wash	24	−13
64490	Inj paravert f jnt c/t 1 lev	24	−16
67042	Vit for macular hole	23	−4
52000	Cystoscopy	21	4
G0260	Inj for sacroiliac jt anesth	21	−5
50590	Fragmenting of kidney stone	21	−1
64555	Implant neuroelectrodes	19	19
67904	Repair eyelid defect	19	2

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2017 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2017. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with section 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2017, the beneficiary coinsurance amount under the ASC payment system generally would be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*, we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 33 below, illustrates the classification of expenditures for the proposed CY 2017 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2017 OPD fee schedule increase, based on the 2016 Trustee's Report,. The second accounting statement, Table 34 below, illustrates the classification of expenditures associated with the proposed 1.2 percent CY 2017 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2016 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 33—ACCOUNTING STATEMENT: PROPOSED CY 2017 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2016 TO CY 2017 ASSOCIATED WITH THE PROPOSED CY 2017 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$671 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$671 million.

TABLE 34—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2016 TO CY 2017 AS A RESULT OF THE PROPOSED CY 2017 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$39 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$39 million.

d. Effects of Proposed Requirements for the Hospital OQR Program

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70593 through 70594) for the estimated effects of changes to the Hospital OQR Program for the CY 2018 payment determination. In section XIII. of this proposed rule, we are proposing changes to policies affecting the Hospital OQR Program. Of the 3,266 hospitals that met eligibility requirements for the CY 2016 payment determination, we determined that 113 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (71 of the 113) chose not to participate in the Hospital OQR Program for the CY 2015 payment determination. We estimate that approximately 108 to 121 hospitals would not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this proposed rule, we are proposing to make several changes to the Hospital OQR Program for the CY 2018 payment determination and subsequent years, CY 2019 payment determination and subsequent years, and the CY 2020 payment determination and subsequent years. We note that while there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of the other changes we are proposing would increase burden, as further discussed below.

For the CY 2018 payment determination and subsequent years, we are proposing to publicly display data on the *Hospital Compare* Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that hospitals will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We do not anticipate additional burden to hospitals as a result of these proposed changes to the public display policies because hospitals would not be required to submit additional data or forms to CMS.

For the CY 2019 payment determination and subsequent years, we are proposing to extend the time for filing an extraordinary circumstance exception or exemption request from 45 days to 90 days. We do not anticipate additional burden to hospitals as a result of this proposal because the requirements for filing a request have not otherwise changed.

For the CY 2020 payment determination and subsequent years, we are proposing to adopt two new claims-based measures for the Hospital OQR Program: OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687). For the CY 2020 payment determination and subsequent years, we also are proposing to adopt five new OAS CAHPS Survey-based measures: (1) OP–37a: OAS CAHPS—About Facilities and Staff; (2) OP–37b: OAS CAHPS—Communication About Procedure; (3) OP–37c: OAS CAHPS—Preparation for Discharge and Recovery; (4) OP–37d: OAS CAHPS—Overall Rating of Facility; and (5) OP–37e: OAS CAHPS—Recommendation of Facility. As discussed in section XXI.B.3. of this proposed rule, we do not believe that the OP–35 and OP–36 measures would create any additional burden across all participating hospitals because these measures use Medicare FFS claims data and do not require additional hospital data submissions. In addition, as discussed in the same section, the burden associated with the proposed OAS CAHPS Survey-based measures (proposed OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) is already accounted for in previously approved OMB Control Number 0938–1240.

We refer readers to section XXI.B. of this proposed rule (information collection requirements) for a detailed discussion of the burden of the proposed additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

In section XIV. of this proposed rule, we discuss our proposals to adopt policies affecting the ASCQR Program. For the CY 2016 payment determination, of the 5,260 ASCs that met eligibility requirements for the ASCQR Program, 261 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70594), we used the CY 2015 payment determination numbers as a baseline, and estimated that approximately 115 ASCs will not receive the full annual payment update in CY 2018 due to failure to meet the ASCQR Program requirements (CY 2016 and CY 2017 payment determination information were not yet available).

For the CY 2018 payment determination and subsequent years, we are making a few proposals. In section XIV.B.7. of this proposed rule, we are proposing to publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, we are proposing that ASCs will generally have approximately 30 days to preview their data. Both of these proposals are consistent with current practice. Lastly, we are proposing to announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs. We believe that these proposed changes to the ASCQR Program public reporting policies will have no effect on burden for ASCs because these changes would not require participating ASCs to submit additional data to CMS.

For the CY 2019 payment determination and subsequent years, we are making two new proposals. In section XIV.D.3. of this proposed rule, we are proposing to implement a submission deadline with an end date of May 15 for all data submitted via a Web-based tool (CMS or non-CMS) beginning with the CY 2019 payment determination. We do not anticipate additional burden as the data collection and submission requirements have not changed; only the deadline would be moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. In section XIV.D.6. of this proposed rule, we are proposing to extend the time for filing an extraordinary circumstance exception or exemption request from 45 days to 90 days. We do not believe this proposal will result in additional burden to ASCs because the requirements for filing a request have not otherwise changed. We are not proposing to add any quality measures to the ASCQR measure set for the CY 2019 payment determination, nor do we believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66978 through 66979) for a list of these measures.) Therefore, we do not believe that these proposals would increase the number of ASCs that do not receive a full annual payment update for the CY 2019 payment determination.

In section XIV.B.4. of this proposed rule, we are proposing to add two new measures collected via a CMS online data submission tool to the ASCQR program measure set for the CY 2020 payment determination—ASC–13: Normothermia Outcome and ASC–14: Unplanned Anterior Vitrectomy—and five new OAS CAHPS Survey-based measures for the CY 2020 payment determination: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility. As discussed in section XXI.C.2. of this proposed rule, we estimate a data collection and submission burden of approximately 15.75 hours and $517 (15.75 hours × $32.84 per hour) each per ASC for the proposed ASC–14 and ASC–14 measures based on an average sample of 63 cases. This results in a total estimated burden of approximately 82,845 hours and $2,720,630 for proposed ASC–13 and ASC–14 measures across all ASCs based on an average sample of 63 cases per ASC. In addition, and as discussed in the same section, the burden associated with the proposed OAS CAHPS Survey-based measures is already accounted for in a previously approved OMB Control Number 0938–1240.

We refer readers to the information collection requirements in section XXI.C.2. of this proposed rule for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

f. Effects of the Proposed Changes to Transplant Performance Thresholds

In section XV. of this proposed rule, we discuss proposed changes to the transplant centers performance thresholds to restore the tolerance range for patient and graft survival with respect to organ transplants to those we established in our 2007 regulations. We considered the option of leaving the current regulation unchanged. However, given the recent upward trend in the percent of unused adult kidneys, combined with an increase in the number of recovered organs, we do not believe that inaction is advisable. In addition, in the original 2007 organ transplant rule, CMS committed to review the outcomes thresholds if it considered them to be set at a level that was too high or too low. We are following through on that commitment.

We considered the option of leaving the regulation unchanged and instead reclassifying a larger range of outcomes as a "standard-level" rather than the more serious "condition-level" deficiency. We have already taken this approach to a considerable extent in survey and certification guidance (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html*). However, standard-level deficiencies must be remedied at some point; therefore, reclassification may not yield the change necessary to ensure that the barrier presented by an increasingly stringent outcomes requirement.

We considered the option of creating a "balancing measure" that would directly measure a transplant program's effectiveness in using organs, including tracking organs that are declined to see if other programs were able to make use of the organs successfully for long term graft survival. Such a balancing measure could "unflag" a program that had been flagged for substandard outcomes under the existing outcome measures. The OPTN developed a concept paper to obtain public comment for a similar idea, in which highest risk organs might be removed from the data when calculating outcomes (*https://optn.transplant.hrsa.gov/governance/public-comment/performance-metrics-concept-paper/*). This concept is slightly different than use of a balancing measure, but both approaches would require a multiyear effort to construct, test, and study the effects, including potential undesirable side effects. It is not an option readily available.

We considered the argument that the regulation should be unchanged because CMS should expect health care providers to improve outcomes over time, and if the outcomes standard is becoming more difficult to meet, providers should rise to the challenge. We agree that we should expect health care providers to improve outcomes over time. However, once programs are at a very high level of performance, there is little room to improve. Therefore, there is no persuasive reason to leave the regulations unchanged. First, in addition to patient and graft survival, we are interested in optimizing the use of organs so that individuals on the waiting list can gain the benefits of a transplant. To the extent that there are unintended and undesirable effects on this access goal as a result of an increasingly stringent outcomes requirement, we believe we should respond. Second, the transplant community has demonstrated a track record of consistent improvement efforts and innovation. Third, we commissioned a study that found that the overall risk levels of both available organs and transplant candidates have been increasing every year.[128] To the extent these population trends continue (for example, increasing age, higher rates of diabetes, obesity, hypertension), transplant programs will continue to be challenged to improve their care and processes just to sustain the patient and graft survival rates already achieved. We will continue to monitor these trends.

Finally, we considered the option to adopt the Bayesian methodology that the OPTN recently adopted. We are not doing so at this time because the OPTN continues to study its implementation of that methodology and to evaluate its own thresholds for flagging programs in relation to the Bayesian model.

We believe that these proposed changes would result in costs savings to hospitals. The savings results from: (1) Fewer programs that would need to file a request for approval on the basis of mitigating factors; and (2) fewer programs that would need to fulfill the terms of an SIA. Both a mitigating factors review and completion of an SIA are voluntary acts on the part of a hospital that maintains a transplant program. Since the 2007 effective date of the CMS regulation, only one hospital has not filed a request for mitigating factors review after being cited by CMS for a condition-level deficiency for patient outcomes or clinical experience, and few hospitals have declined a CMS offer to complete an SIA. Therefore, we have concluded that the costs involved in these activities are much lower for the hospital compared with other alternatives, such as filing an appeal and incurring the legal costs of that appeal.

In the two SRTR reports from 2015, a total of 54 programs were flagged once (24 of which were adult kidney programs). If the proposed performance threshold were set at 1.85 instead of the existing 1.5, this number would have been reduced to 48 programs (21 of which would have been adult kidney programs). However, the cost savings would occur mainly for programs that were multiple-flagged and met the criteria for citation at the condition-level. These are the programs that are cited at the condition level and risk termination of Medicare approval unless they are approved under the mitigating factors provision, and some of those programs would not be approved without successful completion of an SIA. Historically, of the programs that voluntarily withdrew from Medicare participation pending termination or were terminated based on outcomes deficiencies for which data are available, all had O/E ratios above the proposed performance threshold of 1.85. For CY 2015, a total of 30 programs met the criteria for condition-level deficiency (15 of which were adult kidney programs). If the threshold had been at the 1.85 instead of 1.5 level, these numbers would have been reduced to 27 and 13 respectively.

We estimate the cost associated with the application for mitigating factors at $10,000. This is based on the salary for the transplant administrator to prepare the documents for the application during the 30-day timeframe allotted. Based on the CY 2015 SRTR reports described earlier, we estimate that three fewer programs each year would need to file a mitigating factors request, yielding a small savings of $30,000 per year.

We also estimate that four fewer programs each year would be required to complete an SIA. For transplant programs that enter into an SIA, the estimated cost to the transplant program is $250,000 based on reports from programs that have completed such agreements in the past. Therefore, we estimate the annual cost savings to hospitals from fewer SIAs to be $1 million.

We estimate that the total costs savings would be $1 million per year ($1 million plus $30,000), and conclude that our proposed policies would not have a significant impact on a substantial number of small businesses or other small entities. Nor would they have a significant impact on small rural hospitals.

---

[128] White, Zinsser et al., "Patient Selection and Volume in the Era Surrounding Implementation of Medicare Conditions of Participation for Transplant Programs," *Health Services Research*, DOI: 10.111/1465–6773.12188.

g. Effects of the Proposed Changes Relating to Organ Procurement Organizations (OPOs)

In section XVI. of this proposed rule, we discuss our proposals to expand and clarify the current OPO regulation as it relates to revising the definition of eligible death, adjusting the outcome performance yield measure and changing the documentation requirements of donor information to the transplant center to align CMS policy with OPTN policy and the SRTR yield metric.

All 58 OPOs would be affected by the proposed requirements to a greater or lesser degree. Many OPOs have already put into practice many of the proposed requirements. Thus, while we do not believe these proposals would have a substantial economic impact on a significant number of OPOs, we believe it is desirable to inform the public of our projections of the likely effects of these proposals on OPOs. It is important to note that because OPOs are paid by the Medicare program on a cost basis, any additional costs that exceed an OPO's annual revenues would be fully paid under the Medicare program. In addition, these proposals would have no identifiable economic impact on transplant hospitals. It is expected that improved OPO performance would result from the proposals and increase organ donation and the number of organs available for transplantation.

The proposed definition and yield metric changes would result in no additional burden. OPOs already report a large amount of data to the OPTN which, in turn, provides the data to the SRTR for analysis. OPOs would not be asked to report additional data as a result of the proposals.

The proposal to change the documentation requirements of donor information sent to the transplant center with the organs would reduce burden for the OPOs. This proposed change would reduce the amount of hard copy documentation that is packaged and shipped with each organ and would free up the OPO transplant coordinator's time to focus on the critical donor management and organ preparation tasks. We estimate that this proposed change would save OPOs a total of approximately $259,000 a year for all 58 certified OPOs. There were approximately 7,000 deceased eligible donors in 2014 (according to the CMS data report), which would require hard copy documentation packaged and shipped with the organ(s) procured by the OPO transplant coordinator. According to *http://www.payscale.com/*, the average salary for an OPO transplant coordinator is $70,693 per year, which is approximately $37 an hour. We estimate that it takes an OPO transplant coordinator approximately 1 hour to print, package, and ship the hard copy documentation with the organ(s) at $37 an hour for approximately 7,000 deceased donors. Thirty-seven dollars an hour multiplied by 7,000 deceased donors which require hard copy documentation equals $259,000 and 7,000 hours saved for OPOs nationwide.

The primary economic impact of these proposals would lie with their potential to increase organ donation. However, it is difficult to predict precisely what that impact would be, but we estimate that, by increasing OPOs' efficiency and adherence to continuous quality improvement measures, these proposals could increase the number of organ donors in the regulation's first year.

With regard to the impact of the proposed OPO transplant enforcement technical corrections discussed in section XVII. of this proposed rule, there is no economic impact.

h. Effects of the Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

In section XVIII. of this proposed rule, we discuss proposed requirements for the Medicare and Medicaid EHR Incentive Programs. Specifically, in this proposed rule, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, we are proposing to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for Modified Stage 2 and Stage 3 as well as to reduce the reporting thresholds on a subset of the remaining objectives and measures to the Modified Stage 2 thresholds. We do not believe that the proposals would increase burden on eligible hospitals and CAHs as the objectives and measures remain the same, only a subset of thresholds would be reduced. In addition, the proposals to eliminate the CDS and CPOE objectives and measures are based on high performance and the statistical evidence demonstrates that the expected result of any provider attesting to the EHR Incentive Programs would be a score near the maximum. While the functions of measures and the processes behind them would continue even without a requirement to report the results, the provisions would result in a reduction in reporting requirements.

We are also proposing to modify the EHR reporting period in 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use to any continuous 90-day period within CY 2016. We do not believe that the modification of the EHR reporting period in 2016 to any continuous 90-day period would increase the reporting burden of providers in the Medicare and Medicaid EHR Incentive Programs as all providers attested to a 90-day EHR reporting period in 2015.

We are proposing to modify the options for reporting on Modified Stage 2 or Stage 3 objectives finalized in the 2015 EHR Incentive Programs final rule by requiring new participants in 2017 who are seeking to avoid the 2018 payment adjustment to attest to the Modified Stage 2 objectives and measures. We do not believe proposing to require new participants in 2017 to attest to Modified Stage 2 objectives and measures would increase the reporting burden because new participants using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

We are proposing that for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. Because this proposal only affect the time period within which certain actions must occur, but not the underlying actions to be reported, we do not believe that this proposal would affect the burden on meaningful users.

Finally, we are proposing a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017. We do not believe the proposal to allow a one-time significant hardship exception from the 2018 payment adjustment for certain EPs would increase their burden, rather, we believe this would reduce the reporting burden for 2017 because this proposal would reduce confusion on the different reporting requirements for the EHR Incentive Program and MIPs as well as the different systems to which participants would need to register and attest.

i. Effects of Proposed Requirements for the Hospital VBP Program

In section XIX. of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to remove the HCAHPS Pain Management dimension in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

As required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is included the Hospital IQR Program. Therefore, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. The proposed removal of the HCAHPS Pain Management dimension from the Hospital VBP Program also would not result in any additional reporting burden.

j. Effects of Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating To Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

In section X.A. of this proposed rule, we discuss the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 relating to payments for certain items and services furnished by certain off-campus departments of a provider. Section 603 does not impact OPPS payment rates or payments to OPPS-eligible providers. The impact tables displayed in section XXIII.A.3. of this proposed rule do not factor in changes in volume or service-mix in OPPS payments. As a result, the impact tables displayed in section XXIII.A.3. of this proposed rule do not reflect changes in the volume of OPPS services due to the implementation of section 603.

We estimate that implementation of section 603 will reduce net OPPS payments by $500 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. We estimate that section 603 would increase payments to physicians under the MPFS by $170 million in CY 2017, resulting in a net Medicare Part B impact from the provision of reducing CY 2017 Part B expenditures by $330 million. These estimates include both the FFS impact of the provision and the Medicare Advantage impact of the provision. These estimates also reflect that the reduced spending from implementation of section 603 results in a lower Part B premium; the reduced Part B spending is slightly offset by lower aggregate Part B premium collections.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's "Table of Small Business Size Standards" at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 634 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $146 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2017. Table 31 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.6 percent increase in payments for all services paid under the OPPS in CY 2017, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2017.

The proposed updates to the ASC payment system for CY 2017 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 32 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 1.2 percent for CY 2017.

XXV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 30 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.6 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 416.171 is amended by revising paragraph (b)(2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(2) The device portion of device-intensive procedures, which are procedures with a HCPCS code-level device offset of greater than 40 percent when calculated according to the standard OPPS APC ratesetting methodology.

* * * * *

■ 3. Section 416.310 is amended by revising paragraphs (c)(1)(ii) and (d)(1) and adding paragraph (e) to read as follows:

§ 416.310. Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(ii) *Data collection requirements.* The data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year.

* * * * *

(d) * * *

(1) Upon request of the ASC. ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

* * * * *

(e) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Ambulatory surgical centers must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS survey as a vendor on behalf of one or more ambulatory surgical centers when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Web site.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 4. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 5. Section 419.22 is amended by adding paragraph (v) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(v) Effective January 1, 2017, for cost reporting periods beginning on or after January 1, 2017, items and services that are provided by an off-campus provider-based department (as defined at § 419.48(b)) that do not meet the definition of excepted items and services under § 419.48(a).

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(8) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*8*) For calendar year 2017, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.43 is amended by adding paragraph (d)(7) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(d) * * *

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC's total outlier payments for the calendar year do not exceed 8 percent of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

* * * * *

■ 8. Section 419.44 is amended by revising paragraph (b)(2) to read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) * * *

(2) For all device-intensive procedures (defined as having a device offset of greater than 40 percent), the device offset portion of the device-intensive procedure payment is subtracted prior to determining the program payment and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

■ 9. Section 419.46 is amended by adding paragraph (g) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(g) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems Survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Hospital outpatient departments must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS Survey as a vendor on behalf of one or more hospital outpatient departments when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Survey Web site. An entity must be an approved OAS CAHPS Survey vendor in order to administer and submit OAS CAHPS Survey data to CMS on behalf of one or more hospital outpatient departments.

■ 10. Section 419.48 is added to subpart D to read as follows:

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) In a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an off-campus provider-based department that submitted a bill for a covered OPD service prior to November 2, 2015, are furnished at the same location that the department was furnishing such services as of November 1, 2015, and are in the same clinical family of services as the services that the department furnished prior to November 2, 2015.

(b) For the purpose of this section, "off-campus provider-based department" means a department of a provider (as defined at § 413.65(a)(2) of this chapter as in effect as of November 2, 2015) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a remote location of a hospital (as defined in § 413.65 of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

■ 11. Section 419.66 is amended by revising paragraph (g) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(g) *Limited period of payment for devices.* CMS limits the eligibility of a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment is made.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 12. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 13. Section 482.80 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

■ 14. Section 482.82 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 15. The authority citation for part 486 continues to read as follows:

Authority: 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 16. Section 486.302 is amended by revising the definition of "Eligible death" to read as follows:

§ 486.302 Definitions.

* * * * *

Eligible death. An eligible death for organ donation means the death of a person—

(1) Who is 75 years old or younger;

(2) Who is legally declared dead by neurologic criteria in accordance with State or local law;

(3) Whose body weight is 5 kg or greater;

(4) Whose body mass Index (BMI) is 50 kg/m2 or less;

(5) Who had at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as follows:

(i) The kidney would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

(A) Is more than 70 years of age;

(B) Is age 50–69 years with history of Type 1 diabetes for more than 20 years;

(C) Has polycystic kidney disease;

(D) Has glomerulosclerosis equal to or more than 20 percent by kidney biopsy;

(E) Has terminal serum creatinine greater than 4/0 mg/dl;

(F) Has chronic renal failure; or

(G) Has no urine output for at least or more than 24 hours;

(ii) The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:

(A) Cirrhosis;

(B) Terminal total bilirubin equal to or more than 4 mg/dl;

(C) Portal hypertension;

(D) Macrosteatosis equal to or more than 50 percent or fibrosis equal to or more than stage II;

(E) Fulminant hepatic failure; or

(F) Terminal AST/ALT of more than 700 U/L.

(iii) The heart would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

(A) Is more than 60 years of age;

(B) Is at least or more than 45 years of age with a history of at least or more than 10 years of HTN or at least or more than 10 years of type 1 diabetes;

(C) Has a history of Coronary Artery Bypass Graft (CABG);

(D) Has a history of coronary stent/intervention;

(E) Has a current or past medical history of myocardial infarction (MI);

(F) Has a severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease);

(G) Has acute myocarditis and/or endocarditis;

(H) Has heart failure due to cardiomyopathy;

(I) Has an internal defibrillator or pacemaker;

(J) Has moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair;

(K) Has serial echo results showing severe global hypokinesis;

(L) Has myxoma; or

(M) Has congenital defects (whether surgically corrected or not).

(iv) The lung would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

(A) Is more than 65 years of age;

(B) Is diagnosed with coronary obstructive pulmonary disease (COPD) (for example, emphysema);

(C) Has terminal PaO2/FiO2 less than 250 mmHg;

(D) Has asthma (with daily prescription);

(E) Asthma is the cause of death;

(F) Has pulmonary fibrosis;

(G) Has previous lobectomy;

(H) Has multiple blebs documented on Computed Axial Tomography (CAT) Scan;

(I) Has pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures;

(J) Has bilateral severe pulmonary contusions as per CT

(6) If a deceased person meets the criteria specified in paragraphs (1) through (5) of this definition, the death of the person would be classified as an eligible death, unless the donor meets any of the following criteria:

(i) The donor was taken to the operating room with the intent for the OPO to recover organs for transplant and all organs were deemed not medically suitable for transplantation; or

(ii) The donor exhibits any of the following active infections (specific diagnoses) of—

(A) Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel or intra-abdominal sepsis;

(B) Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile (c) Virus infection, SARS, except as provided in paragraph (8) of this definition.

(C) Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection;

(D) Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.); or

(E) Prion: Creutzfeldt-Jacob Disease.

(7) The following are general exclusions:

(i) Aplastic anemia, Agranulocytosis;

(ii) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease;

(iii) Previous malignant neoplasms with current evident metastatic disease;

(iv) A history of melanoma;

(v) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma;

(vi) Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis; and

(vii) No discernable cause of death.

(8) Notwithstanding paragraph (6)(ii)(B) of this definition, an HIV positive organ procured for the purpose of transplantation into an HIV positive recipient would be an exception to an active infection rule out.

* * * * *

■ 17. Section 486.318 is amended by revising paragraphs (a)(3) and (b)(3) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(3) At least 2 of the 3 yield measures specified in paragraph (a)(3)(i) of this section are no more than 1 standard deviation below the national mean, averaged over the 4 years of the recertification cycle, and the OPO data reports must meet the rules and requirements of the most current OPTN aggregate donor yield measure:

(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

(A) A difference of at least 11 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10);

(B) A ratio of observed to expected yield less than 0.90; and

(C) A two-sided p-value is less than 0.05.

(ii) The yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)).

(b) * * *

(3) At least 2 out of the 3 following yield measures specified in paragraph (b)(3)(i) of this section are no more than 1 standard deviation below the national mean, averaged over the 4 years of the recertification cycle, and the OPO data reports must meet the rules and requirements of the most current OPTN aggregate donor yield measure:

(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

(A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10);

(B) A ratio of observed to expected yield less than 0.90; and

(C) A two-sided p-value is less than 0.05.

(ii) The yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)).

* * * * *

■ 18. Section 486.346 is amended by revising paragraph (b) to read as follows:

§ 486.346 Condition: Organ preparation and transport.

* * * * *

(b)(1) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. This information is available to the transplant center electronically.

(2) The OPO must physically send a paper copy of the following documentation with each organ:

(i) Blood type;

(ii) Blood subtype, if used for allocation; and

(iii) Infectious disease testing results available at the time of organ packaging.

(3) The source documentation must be placed in a watertight container in either of the following:

(i) A location specifically designed for documentation; or

(ii) Between the inner and external transport materials.

(4) Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 19. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

■ 20. Section 488.61 is amended by revising paragraphs (f)(1) introductory text, (f)(3), and (h)(2) to read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

* * * * *

(f) * * *

(1) *Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements of § 482.80 or § 482.82 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial and re-approval of a transplant center that does not meet the data submission, clinical experience, or outcome requirements:

* * * * *

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 or § 482.82 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. However, CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

* * * * *

(h) * * *

(2) *Timeframe.* A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period. A signed Systems Improvement Agreement remains in force even if a subsequent SRTR report indicates that the program has restored compliance with the CMS conditions of participation, except that CMS in its sole discretion may shorten the timeframe or allow modification to any portion of the elements of the Agreement in such a case.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 21. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 22. Section 495.4 is amended by—

■ a. In the definition of "EHR reporting period" revising paragraphs (1)(ii)(B)(*2*) and (2)(ii)(B)(*2*).

■ b. In the definition of "EHR reporting period for a payment adjustment year" revising paragraphs (1)(ii)(B)(*2*), (2)(ii)(B)(*2*), and (3)(ii)(B)(*2*).

The revisions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(ii) * * *

(B) * * *

(*2*) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2016.

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2016.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(1) * * *

(ii) * * *

(B) * * *

(*2*) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the CY 2018 payment adjustment year.

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(*2*) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the FY 2018 payment adjustment year.

* * * * *

(3) * * *

(ii) * * *

(B) * * *

(*2*) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the FY 2016 payment adjustment year.

* * * * *

■ 23. Section 495.22 is amended by revising paragraphs (a), (c)(1) introductory text, (d)(1), (e) subject heading, and adding paragraph (f) to read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2017.

(a) *General rules.* (1) Subject to the provisions of paragraph (a)(2) of this section, the criteria specified in this section are applicable for EPs, eligible hospitals and CAHs for 2015 through 2017.

(2) For 2017 only, EPs, eligible hospitals and CAHs that have successfully demonstrated meaningful use in a prior year have the option to use the criteria specified for 2018 in § 495.24 instead of the criteria specified for 2017 under paragraphs (e) and (f) of this section.

* * * * *

(c) * * *

(1) *General rule regarding criteria for meaningful use for 2015 through 2017 for eligible hospitals and CAHs.* Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 and 2016 and must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (f) of this section to meet the definition of a meaningful EHR user in 2017. Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs attesting under a

state's Medicaid EHR Incentive Program must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user in 2015 through 2017.

* * * * *

(d) * * *

(1) If a measure (or associated objective) in paragraph (e) or (f) of this section references paragraph (d) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

* * * * *

(e) *Meaningful use objectives and measures for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2015 and 2016, and for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2015 through 2017.*

* * * * *

(f) *Meaningful use objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2017.*—(1) *Protect patient health information*—(i) *Objective.* Protect electronic protected health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

(ii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary, and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) [Reserved]

(3) [Reserved]

(4) *e-Rx (electronic prescribing)*—(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *e-Prescribing measure.* Subject to the provisions of paragraph (d) of this section, more than 10 percent of hospital discharge medication orders for permissible prescriptions are queried for a drug formulary and transmitted electronically using CEHRT.

(iii) *Exclusion for nonapplicable objectives.* Subject to the provisions of paragraph (c)(2) of this section, any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

(5) *Health Information Exchange*—(i) *Objective.* The eligible hospital or CAH who transitions a patient to another setting of care or provider of care or refers a patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *Health information exchange measure.* Subject to the provisions of paragraph (d) of this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care must do the following:

(A) Use CEHRT to create a summary of care record; and

(B) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(6) *Patient specific education*—(i) *Objective.* Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

(ii) *Patient-specific education measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient specific education resources identified by CEHRT.

(7) *Medication reconciliation.*—(i) *Objective.* The eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant performs medication reconciliation.

(ii) *Medication reconciliation measure.* Subject to the provisions of paragraph (d) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(8) *Patient electronic access*—(i) *Objective.* Provide patients the ability to view online, download, and transmit information within 36 hours of hospital discharge.

(ii) *Measures.* An eligible hospital or CAH must meet the following two measures:

(A) *Patient access measure.* More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have timely access to view online, download, and transmit to a third party their health information.

(B) *View, download, transmit (VDT) measure.* At least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads, or transmits to a third party his or her information during the EHR reporting period.

(iii) *Exclusion for nonapplicable objectives.* Subject to the provisions of paragraph (c)(2) of this section, any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (f)(8)(ii)(B) of this section.

(9) *Public health reporting*—(i) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (f)(9)(i) of this section, an eligible hospital or CAH must choose from measures 1 through 4 (as described in paragraphs (f)(9)(ii)(A) through (D) of this section).

(A) *Immunization measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data.

(B) *Syndromic surveillance measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data.

(C) *Specialized registry measure.* The eligible hospital or CAH is in active engagement to submit data to a specialized registry.

(D) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions for non-applicable objectives.* Subject to the provisions of paragraph (c)(2) of this section—

(A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization measure specified in paragraph (f)(9)(ii)(A) of this section if the eligible hospital or CAH—

(*1*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the eligible hospital or CAH at the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance measure specified in paragraph (f)(9)(ii)(B) of this section if the eligible hospital or CAH—

(*1*) Does not have an emergency or urgent care department.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the specialized registry measure specified in paragraph (f)(9)(ii)(C) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease associated with or collect relevant data is required by a specialized registry for which the eligible hospital or CAH is eligible in their jurisdiction.

(*2*) Operates in a jurisdiction for which no specialized registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

(*3*) Operates in a jurisdiction where no specialized registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(D) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (f)(9)(ii)(D) of this section if the eligible hospital or CAH—

(*1*) Does not perform or order laboratory tests that are reportable in the eligible hospital's or CAH's jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.

■ 24. Section 495.24 is revised to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2018 and subsequent years.

The criteria specified in paragraphs (c) and (d) of this section are optional for 2017 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year. The criteria specified in paragraph (c) of this section are applicable for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2018. The criteria specified in paragraph (d) of this section are applicable for all EPs for 2018 and subsequent years, and for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2018.

(a) *Stage 3 criteria for EPs*—(1) *General rule regarding Stage 3 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) and (3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An EP may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective

(3) *Exclusion for non-applicable objectives and measures.* (i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(*1*) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(*2*) Attests to the exclusion or exclusions.

(B)(*1*) Meets the threshold; and

(*2*) Attests to any remaining measure or measures.

(4) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement, or upgrade its CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(5) *Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in paragraph (d) of this section references paragraph (a)(5) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference this paragraph (a)(5) of this section, the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(b) *Stage 3 criteria for meaningful use for eligible hospitals and CAHs*—(1) *General rule.* Except as specified in paragraphs (b)(2) and (3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraphs (c) and (d) of this section, as applicable, to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraphs (c) and (d) of this section.* An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital

or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (c) or (d) of this section, as applicable, includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for nonapplicable objectives and measures.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraph (c) or (d) of this section, as applicable, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(*1*) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(*2*) Attests to the exclusion or exclusions.

(B)(*1*) Meets the threshold; and

(*2*) Attests to any remaining measure or measures.

(4) *Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals or CAHs that adopt, implement or upgrade CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (c) or (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(5) *Objectives and associated measures in paragraph (c) or (d) of this section that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in paragraph (c) or (d) of this section, as applicable, references paragraph (b)(5) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference this paragraph (b)(5) of this section, the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(c) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2018.*—(1) *Protect patient health information.* (i) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(ii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(2) *eRx (electronic prescribing).*—(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *e-Prescribing measure.* Subject to paragraph (b)(5) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) [Reserved]

(4) [Reserved]

(5) *Patient electronic access to health information.*—(i) *Objective.* The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(ii) *Measures.* Eligible hospitals and CAHs must meet the following two measures:

(A) *Patient access measure.* For more than 50 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(*1*) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(*2*) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(B) *Patient specific education measure.* The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (c)(5)(ii)(A) and (B) of this section.

(6) *Coordination of care through patient engagement.*—(i) *Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(ii) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraphs (c)(6)(ii)(A), (B), and (C) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(A) *View, download, transmit (VDT) measure.* During the EHR reporting period, at least one unique patient (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following:

(*1*) View, download or transmit to a third party their health information.

(*2*) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(*3*) A combination of paragraphs (c)(6)(ii)(A)(*1*) and (*2*) of this section.

(B) *Secure messaging.* During the EHR reporting period, more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient authorized representative), or in response to a secure message sent by the patient (or the patient authorized representative).

(C) *Patient generated health data measure.* Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(iii) *Exclusions under paragraph (b)(3) of this section.* Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (c)(6)(ii)(A), (B), and (C) of this section.

(7) *Health information exchange*—(i) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(ii) *Measures.* In accordance with paragraph (b)(2) of this section, a eligible hospital or CAH must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraphs (e)(7)(ii)(A), (B), and (C) of this section. Subject to paragraph (b)(5) of this section—

(A) *Patient care record exchange measure.* For more than 10 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(*1*) Creates a summary of care record using CEHRT; and

(*2*) Electronically exchanges the summary of care record.

(B) *Request/accept patient care record measure.* For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

(C) *Clinical information reconciliation measure.* For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(*1*) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(*2*) *Medication allergy.* Review of the patient's known allergic medications.

(*3*) *Current problem list.* Review of the patient's current and active diagnoses.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* (A) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (c)(7)(ii)(B) and (C) of this section.

(B) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may be excluded from the measures specified in paragraphs (e)(7)(ii)(A) and (B) of this section.

(8) *Public health and clinical data registry reporting*—(i) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (c)(8)(i) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (c)(8)(ii)(A) through (F) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting the measure specified in paragraphs (c)(8)(ii)(D) and (E) of this section multiple times, in accordance with applicable law and practice:

(A) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(B) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(C) *Case reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(D) *Public health registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(E) *Clinical data registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(F) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions in accordance with paragraph (b)(3) of this section.* (A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (c)(8)(ii)(A) of this section if the eligible hospital or CAH—

(*1*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (c)(8)(ii)(B) of this section if the eligible hospital or CAH—

(*1*) Does not have an emergency or urgent care department.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (e)(8)(ii)(C) of this section if the eligible hospital or CAH—

(*1*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(D) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (c)(8)(ii)(D) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(E) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (c)(8)(ii)(E) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(F) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (c)(8)(ii)(F) of this section if the eligible hospital or CAH—

(*1*) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

(d) *Stage 3 objectives and measures for all EPs for 2018 and subsequent years, and for eligible hospitals and CAHs attesting under a State's Medicaid EHR Incentive Program for 2018*—(1) *Protect patient health information*—(i) *EP protect patient health information*—(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(ii) *Eligible hospital/CAH protect patient health information*—(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(2) *eRx (electronic prescribing)*—(i) *EP eRx (electronic prescribing)*—(A) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(B) *e-Prescribing measure.* Subject to paragraph (a)(5) of this section, more than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (*1*) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(*2*) Any EP who does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

(ii) *Eligible hospital/CAH eRx (electronic prescribing)*—(A) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) *e-Prescribing measure.* Subject to paragraph (b)(5) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) *Clinical decision support*—(i) *EP clinical decision support*—(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.* (*1*) *Clinical decisions support intervention measure.* Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(*2*) *Drug interaction and drug allergy checks measure.* The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) *Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) *Eligible hospital/CAH clinical decision support*—(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures*—(1) *Clinical decisions support intervention measure.* Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(*2*) *Drug interaction and drug allergy checks measure.* The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(4) *Computerized provider order entry (CPOE)*—(i) *EP CPOE*—(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (a)(5) of this section—

(*1*) *Medication orders measure.* More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(*2*) *Laboratory orders measure.* More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(*3*) *Diagnostic imaging orders measure.* More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (*1*) For the measure specified in paragraph (d)(4)(i)(B)(*1*) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(*2*) For the measure specified in paragraph (d)(4)(i)(B)(*2*) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(*3*) For the measure specified in paragraph (d)(4)(i)(B)(*3*) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) *Eligible hospital and CAH CPOE*—(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per State, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (b)(5) of this section—

(*1*) *Medication orders measure.* More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

(*2*) *Laboratory orders measure.* More than 60 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

(*3*) *Diagnostic imaging orders measure.* More than 60 percent of diagnostic imaging orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(5) *Patient electronic access to health information*—(i) *EP patient electronic access to health information*—(A) *Objective.* The EP provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures.* EPs must meet the following two measures:

(*1*) *Patient access measure.* For more than 80 percent of all unique patients seen by the EP—

(*i*) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(*ii*) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(*2*) *Patient specific education measure.* The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (*1*) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(*1*) and (*2*) of this section.

(*2*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(*1*) and (*2*) of this section.

(ii) *Eligible hospital and CAH patient electronic access to health information*—(A) *Objective.* The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures.* Eligible hospitals and CAHs must meet the following two measures:

(*1*) *Patient access measure.* For more than 80 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(*i*) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(*ii*) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(*2*) *Patient specific education measure.* The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusion in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (d)(5)(ii)(B)(1) and (2) of this section.

(6) *Coordination of care through patient engagement*—(i) *EP coordination of care through patient engagement*—(A) *Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(*1*), (*2*), and (*3*) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(*1*) *View, download, transmit (VDT) measure.* During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and either of the following:

(*i*) View, download or transmit to a third party their health information;

(*ii*) their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(*iii*) A combination of paragraphs (d)(6)(i)(B)(*1*)(*i*) and (*ii*) of this section.

(*iv*) For an EHR reporting period in 2017 only, an EP may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(i)(B)(*1*) of this section.

(*2*) During the EHR reporting period—

(*i*) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient; or

(*ii*) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(*3*) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (*1*) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(*1*), (*2*), and (*3*) of this section.

(*2*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(*1*), (*2*), and (*3*) of this section.

(ii) *Eligible hospital and CAH coordination of care through patient engagement*—(A) *Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraphs (d)(6)(ii)(B)(*1*), (*2*), and (*3*) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(*1*) *View, download, transmit (VDT) measure.* During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following:

(*i*) View, download or transmit to a third party their health information.

(*ii*) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT.

(*iii*) A combination of paragraphs (d)(6)(ii)(B)(*1*)(*i*) and (*ii*) of this section.

(*iv*) For an EHR reporting period in 2017, an eligible hospital or CAH may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(ii)(B)(*1*) of this section.

(*2*) *Secure messaging measure.* During the EHR reporting period—

(*i*) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(*ii*) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(*3*) *Patient generated health data measure.* Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusions under paragraph (b)(3) of this section.* Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(*1*), (*2*), and (*3*) of this section.

(7) *Health information exchange*—(i) *EP health information exchange*—(A) *Objective.* The EP provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraphs (d)(7)(i)(B)(*1*), (*2*), and (*3*) of this section, in order to meet the objective. Subject to paragraph (c) of this section—

(*1*) *Patient record exchange measure.* For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—

(*i*) Creates a summary of care record using CEHRT; and

(*ii*) Electronically exchanges the summary of care record.

(*2*) *Request/accept patient care record measure.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document.

(*3*) *Clinical information reconciliation measure.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for the following three clinical information sets:

(*i*) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(*ii*) *Medication allergy.* Review of the patient's known allergic medications.

(*iii*) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* An EP must be excluded when any of the following occur:

(*1*) Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period must be excluded from paragraph (d)(7)(i)(B)(*1*) of this section.

(*2*) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(*2*) and (*3*) of this section.

(*3*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(*1*) and (*2*) of this section.

(*ii*) *Eligible hospitals and CAHs health information exchange*—(A) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraphs (d)(7)(ii)(B)(*1*), (*2*), and (*3*) of this section. Subject to paragraph (b)(5) of this section—

(*1*) *Patient record exchange measure.* For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(*i*) Creates a summary of care record using CEHRT; and

(*ii*) Electronically exchanges the summary of care record.

(*2*) Request/accept patient care record measure. For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(*3*) *Clinical information reconciliation measure.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(*i*) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(*ii*) *Medication allergy.* Review of the patient's known allergic medications.

(*iii*) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* (*1*) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(*2*) and (*3*) of this section.

(*2*) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(ii)(B)(*1*) and (*2*) of this section.

(8) *Public Health and Clinical Data Registry Reporting*—(i) *EP Public Health and Clinical Data Registry: Reporting Objective*—(A) *Objective.* The EP is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(*1*) through (*5*) of this section) and must successfully attest to any combination of two measures. These measures may be met by any combination, including meeting measure specified in paragraph (d)(8)(i)(B)(*4*) or (*5*) of this section multiple times, in accordance with applicable law and practice:

(*1*) *Immunization registry reporting measure.* The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(*2*) *Syndromic surveillance reporting measure.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting

(*3*) *Electronic case reporting measure.* The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(*4*) *Public health registry reporting measure.* The EP is in active engagement with a public health agency to submit data to public health registries.

(*5*) *Clinical data registry reporting measure.* The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (*1*) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting measure in paragraph (d)(8)(i)(B)(*1*) of this section if the EP—

(*i*) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of its EHR reporting period.

(*iii*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(*2*) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (d)(8)(i)(B)(*2*) of the section if the EP—

(*i*) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

(*3*) Any EP meeting one or more of the following criteria may be excluded from the case reporting measure at paragraph (d)(8)(i)(B)(*3*) of this section if the EP:

(*i*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(*4*) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(i)(B)(*4*) of this section if the EP—

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in the EP's jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*5*) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(i)(B)(*5*) of this section if the EP—

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry: Reporting objective*—(A) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(*1*) through (*6*) of this section) and must successfully attest to any combination of four measures. These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(ii)(B)(*4*) or (*5*) of this section multiple times, in accordance with applicable law and practice:

(*1*) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(*2*) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(*3*) *Case reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(*4*) *Public health registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(*5*) *Clinical data registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(*6*) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* (*1*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (d)(8)(ii)(B)(*1*) of this section if the eligible hospital or CAH—

(*i*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(*2*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (d)(8)(ii)(B)(*2*) of this section if the eligible hospital or CAH—

(*i*) Does not have an emergency or urgent care department.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(*3*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(ii)(B)(*3*) of this section if the eligible hospital or CAH—

(*i*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(*4*) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(ii)(B)(*4*) of this section if the eligible hospital or CAH—

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*5*) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(ii)(B)(*5*) of this section if the eligible hospital or CAH—

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*6*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(8)(ii)(B)(*6*) of this section if the eligible hospital or CAH—

(*i*) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

■ 25. Section 495.40 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Revising paragraphs (a)(2)(i)(E) and (F).

■ c. Adding paragraph (a)(2)(i)(G).

■ d. Revising paragraphs (b) introductory text and (b)(2)(i)(E) and (F).

■ e. Redesignating paragraph (b)(2)(i)(G) as paragraph (b)(2)(i)(H).

■ f. Adding a new paragraph (b)(2)(i)(G).

The revisions and additions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs.* An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.20 or § 495.24, as follows:

* * * * *

(2) * * *

(i) * * *

(E) For CYs 2015 through 2016, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017: An EP that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(e) for meaningful use or the objectives and measures specified in § 495.24(d) for meaningful use; an EP that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(e) for meaningful use.

(G) For CY 2018 and subsequent years, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate that it is a meaningful EHR user, an eligible hospital or CAH must satisfy the following requirements:

* * * * *

(2) * * *

(i) * * *

(E) For CYs 2015 through 2016, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017:

(*1*) For an eligible hospital or CAH attesting under the Medicare EHR Incentive Program: An eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(f) for meaningful use or the objectives and measures specified in § 495.24(c) for meaningful use; an eligible hospital or CAH that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(f) for meaningful use.

(*2*) For an eligible hospital or CAH attesting under a state's Medicaid EHR Incentive Program: An eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year may satisfy either the objectives and measures specified in § 495.22(e) for meaningful use or the objectives and measures specified in § 495.24(d) for meaningful use; an eligible hospital or CAH that has never successfully demonstrated it is a meaningful EHR user in any prior year must satisfy the objectives and measures specified in § 495.22(e) for meaningful use.

(G) For CY 2018:

(*1*) For an eligible hospital or CAH attesting under the Medicare EHR Incentive Program, satisfied the required objectives and associated measures under § 495.24(c) for meaningful use.

(*2*) For an eligible hospital or CAH attesting under a state's Medicaid EHR Incentive Program, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

■ 26. Section 495.102 is amended by adding paragraph (d)(4)(v) to read as follows:

§ 495.102 Incentive payments to EPs.

* * * * *

(d) * * *

(4) * * *

(v) For the 2018 payment adjustment only, an EP who has not successfully demonstrated meaningful use in a prior year, intends to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017 to avoid the 2018 payment adjustment, and intends to transition to the Merit-Based Incentive Payment System (MIPS) and report on measures specified for the advancing care information performance category under the MIPS in 2017. The EP must explain in the application why demonstrating meaningful use for an EHR reporting period in 2017 would result in a significant hardship. Applications requesting this exception must be submitted no later than October 1, 2017, or a later date specified by CMS.

* * * * *

Dated: June 22, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare and Medicaid Services.

Dated: June 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–16098 Filed 7–6–16; 4:15 pm]

BILLING CODE 4120–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 32
2016–2017 Refuge-Specific Hunting and Sport Fishing Regulations; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

[Docket No. FWS–HQ–NWRS–2016–0007; FXRS12650900000–167–FF09R26000]

RIN 1018–BB31

2016–2017 Refuge-Specific Hunting and Sport Fishing Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to add 1 national wildlife refuge (NWR or refuge) to the list of areas open for hunting, increase the hunting activities available at 12 other NWRs, open 1 refuge to fishing for the first time, and add pertinent refuge-specific regulations for other NWRs that pertain to migratory game bird hunting, upland game hunting, big game hunting, and sport fishing for the 2016–2017 season.

DATES: We will accept comments received or postmarked on or before August 15, 2016.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, type in FWS–HQ–NWRS–2016–0007, which is the docket number for this rulemaking. Then click on the Search button. On the resulting screen, find the correct document and submit a comment by clicking on "Comment Now!"
- *By hard copy:* Submit by U.S. mail or hand delivery: Public Comments Processing, Attn: FWS–HQ–NWRS–2016–0007; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: BPHC; Falls Church, VA 22041–3803.

We will not accept email or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Comments, below, for more information). For information on specific refuges' public use programs and the conditions that apply to them or for copies of compatibility determinations for any refuge(s), contact individual programs at the addresses/phone numbers given in Available Information for Specific Refuges under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Jillian Cohen, (703) 358–1764.

SUPPLEMENTARY INFORMATION: The National Wildlife Refuge System Administration Act of 1966 closes NWRs in all States except Alaska to all uses until opened. The Secretary of the Interior (Secretary) may open refuge areas to any use, including hunting and/or sport fishing, upon a determination that the use is compatible with the purposes of the refuge and National Wildlife Refuge System mission. The action also must be in accordance with provisions of all laws applicable to the areas, developed in coordination with the appropriate State fish and wildlife agency(ies), consistent with the principles of sound fish and wildlife management and administration, and otherwise in the public interest. These requirements ensure that we maintain the biological integrity, diversity, and environmental health of the Refuge System for the benefit of present and future generations of Americans.

We annually review refuge hunting and sport fishing programs to determine whether to include additional refuges or whether individual refuge regulations governing existing programs need modifications. Changing environmental conditions, State and Federal regulations, and other factors affecting fish and wildlife populations and habitat may warrant modifications to refuge-specific regulations to ensure the continued compatibility of hunting and sport fishing programs and to ensure that these programs will not materially interfere with or detract from the fulfillment of refuge purposes or the Refuge System's mission.

Provisions governing hunting and sport fishing on refuges are in title 50 of the Code of Federal Regulations in part 32 (50 CFR part 32). We regulate hunting and sport fishing on refuges to:

- Ensure compatibility with refuge purpose(s);
- Properly manage fish and wildlife resource(s);
- Protect other refuge values;
- Ensure refuge visitor safety; and
- Provide opportunities for quality fish- and wildlife-dependent recreation.

On many refuges where we decide to allow hunting and sport fishing, our general policy of adopting regulations identical to State hunting and sport fishing regulations is adequate in meeting these objectives. On other refuges, we must supplement State regulations with more-restrictive Federal regulations to ensure that we meet our management responsibilities, as outlined in the Statutory Authority section, below. We issue refuge-specific hunting and sport fishing regulations when we open wildlife refuges to migratory game bird hunting, upland game hunting, big game hunting, or sport fishing. These regulations may list the wildlife species that you may hunt or fish, seasons, bag or creel (container for carrying fish) limits, methods of hunting or sport fishing, descriptions of areas open to hunting or sport fishing, and other provisions as appropriate. You may find previously issued refuge-specific regulations for hunting and sport fishing in 50 CFR part 32. In this rulemaking, we are also proposing to standardize and clarify the language of existing regulations.

Statutory Authority

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee, as amended by the National Wildlife Refuge System Improvement Act of 1997 [Improvement Act]) (Administration Act), and the Refuge Recreation Act of 1962 (16 U.S.C. 460k—460k–4) (Recreation Act) govern the administration and public use of refuges.

Amendments enacted by the Improvement Act built upon the Administration Act in a manner that provides an "organic act" for the Refuge System, similar to organic acts that exist for other public Federal lands. The Improvement Act serves to ensure that we effectively manage the Refuge System as a national network of lands, waters, and interests for the protection and conservation of our Nation's wildlife resources. The Administration Act states first and foremost that we focus our Refuge System mission on conservation of fish, wildlife, and plant resources and their habitats. The Improvement Act requires the Secretary, before allowing a new use of a refuge, or before expanding, renewing, or extending an existing use of a refuge, to determine that the use is compatible with the purpose for which the refuge was established and the mission of the Refuge System. The Improvement Act established as the policy of the United States that wildlife-dependent recreation, when compatible, is a legitimate and appropriate public use of the Refuge System, through which the American public can develop an appreciation for fish and wildlife. The Improvement Act established six wildlife-dependent recreational uses as the priority general public uses of the Refuge System. These uses are: Hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

The Recreation Act authorizes the Secretary to administer areas within the Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that doing so is practicable and not inconsistent with the primary purpose(s) for which Congress and the Service established the areas. The Recreation Act requires that any recreational use of refuge lands be compatible with the primary purpose(s) for which we established the refuge and not inconsistent with other previously authorized operations.

The Administration Act and Recreation Act also authorize the Secretary to issue regulations to carry out the purposes of the Acts and regulate uses.

We develop specific management plans for each refuge prior to opening it to hunting or sport fishing. In many cases, we develop refuge-specific regulations to ensure the compatibility of the programs with the purpose(s) for which we established the refuge and the Refuge System mission. We ensure initial compliance with the Administration Act and the Recreation Act for hunting and sport fishing on newly acquired refuges through an interim determination of compatibility made at or near the time of acquisition. These regulations ensure that we make the determinations required by these acts prior to adding refuges to the lists of areas open to hunting and sport fishing in 50 CFR part 32. We ensure continued compliance by the development of comprehensive conservation plans, specific plans, and by annual review of hunting and sport fishing programs and regulations.

Amendments to Existing Regulations

This document proposes to codify in the Code of Federal Regulations all of the Service's hunting and/or sport fishing regulations that we would update since the last time we published a rule amending these regulations (80 FR 51878; August 26, 2015) and that are applicable at Refuge System units previously opened to hunting and/or sport fishing. We propose this to better inform the general public of the regulations at each refuge, to increase understanding and compliance with these regulations, and to make enforcement of these regulations more efficient. In addition to now finding these regulations in 50 CFR part 32, visitors to our refuges may find them reiterated in literature distributed by each refuge or posted on signs.

We cross-reference a number of existing regulations in 50 CFR parts 26, 27, 28, and 32 to assist hunting and sport fishing visitors with understanding safety and other legal requirements on refuges. This redundancy is deliberate, with the intention of improving safety and compliance in our hunting and sport fishing programs.

TABLE 1—CHANGES FOR 2016–2017 HUNTING/FISHING SEASON

Refuge/Region (*)	State	Migratory bird hunting	Upland game hunting	Big game hunting	Sport fishing
Alamosa (6)	Colorado	D	Already open	B	Closed.
Anahuac (2)	Texas	C/D	Closed	Closed	Already open.
Atchafalaya (4)	Louisiana	Already open	Already open	D	Already open.
Baca (6)	Colorado	A	A	A	Closed.
Black Bayou Lake (4)	Louisiana	C	C	C	Already open.
Buffalo Lake (2)	Texas	Closed	Already open	B	Closed.
Detroit River NWR (3)	Illinois and Missouri	C	C	C	Closed.
Lake Andes (6)	South Dakota	Already open	Already open	Already open	B.
Monte Vista (6)	Colorado	D	Already open	B	Closed.
Montezuma (5)	New York	C/D	Closed	C/D	Already open.
Patoka River (3)	Indiana	C	C	C	C.
Waccamaw (4)	South Carolina	C	C	C	Already open.
Washita (2)	Oklahoma	Already open	Already open	D	Already open

Key:
* number in ( ) refers to the Region as defined in the preamble to this proposed rule under Available Information for Specific Refuges.
A = New refuge opened.
B = New activity on a refuge previously open to other activities.
C = Refuge already open to activity, but added new lands/waters or modified areas open to hunting or fishing.
D = Refuge already open to activity but added new species to hunt.

The changes for the 2016–17 hunting/fishing season noted in the chart above are each based on a complete administrative record which, among other detailed documentation, also includes a hunt plan, a compatibility determination, and the appropriate National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) analysis, all of which were the subject of a public review and comment process. These documents are available upon request. In this proposed rule, we are also proposing to adopt new names for two refuges, White River National Wildlife Refuge and Nisqually National Wildlife Refuge. The new name for White River National Wildlife Refuge is Dale Bumpers White River National Wildlife Refuge, and the new name for Nisqually National Wildlife Refuge is Billy Frank Jr. Nisqually National Wildlife Refuge.

Fish Advisory

For health reasons, anglers should review and follow State-issued consumption advisories before enjoying recreational sport fishing opportunities on Service-managed waters. You can find information about current fish-consumption advisories on the Internet at: *http://www.epa.gov/fish-tech.*

Plain Language Mandate

In this proposed rule, we propose some of the revisions to the individual refuge units to comply with a Presidential mandate to use plain language in regulations; these particular revisions do not modify the substance of the previous regulations. These types of changes include using "you" to refer to the reader and "we" to refer to the Refuge System, using the word "allow" instead of "permit" when we do not require the use of a permit for an activity, and using active voice (*e.g.,* "We restrict entry into the refuge" vs. "Entry into the refuge is restricted").

Request for Comments

You may submit comments and materials on this proposed rule by any one of the methods listed in **ADDRESSES**. We will not accept comments sent by email or fax or to an address not listed in **ADDRESSES**. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in **DATES**.

We will post your entire comment on *http://www.regulations.gov*. Before including personal identifying information in your comment, you should be aware that we may make your entire comment—including your personal identifying information—publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov*.

Public Comment

Department of the Interior policy is, whenever practicable, to afford the public a meaningful opportunity to participate in the rulemaking process. The process of opening refuges is done in stages, with the fundamental work being performed on the ground at the refuge and in the community where the program is administered. In these stages, the public is given other opportunities to comment, for example, on comprehensive conservation plans and compatibility determinations. The second stage is this document, when we publish the proposed rule in the **Federal Register** for additional comment, usually for a 30-day comment period.

There is nothing contained in this proposed rule outside the scope of the annual review process where we determine whether individual refuges need modifications, deletions, or additions made to them. We make every attempt to collect all of the proposals from the refuges nationwide and process them expeditiously to maximize the time available for public review. A 30-day comment period, through the broader publication following the earlier public involvement, gives the public sufficient time to comment and allows us to establish hunting and fishing programs in time for the upcoming seasons. Many of these rules would also relieve restrictions and allow the public to participate in recreational activities on a number of refuges. In addition, in order to continue to provide for previously authorized hunting opportunities while at the same time providing for adequate resource protection, we must be timely in providing modifications to certain hunting programs on some refuges.

We considered providing a 60-day, rather than a 30-day, comment period. However, we determined that an additional 30-day delay in processing these refuge-specific hunting and sport fishing regulations would hinder the effective planning and administration of our hunting and sport fishing programs. Such a delay would jeopardize enacting amendments to hunting and sport fishing programs in time for implementation this year and/or early next year, or shorten the duration of these programs.

Even after issuance of a final rule, we accept comments, suggestions, and concerns for consideration for any appropriate subsequent rulemaking.

When finalized, we will incorporate these regulations into 50 CFR part 32. Part 32 contains general provisions and refuge-specific regulations for hunting and sport fishing on refuges.

Clarity of This Proposed Rule

Executive Orders 12866 and 12988 and the Presidential Memorandum of June 1, 1998, require us to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rulemaking is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act [SBREFA] of 1996) (5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for "significant impact" and a threshold for a "substantial number of small entities." See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule adds 1 national wildlife refuge to the list of refuges open to hunting and increases hunting or fishing activities on 12 additional national wildlife refuges. It adds 1 national wildlife refuge to the list of refuges open to fishing. As a result, visitor use for wildlife-dependent recreation on these NWRs will change. If the refuges establishing new programs were a pure addition to the current supply of those activities, it would mean an estimated increase of 4,045 user days (one person per day participating in a recreational opportunity, Table 2). Because the participation trend is flat in these activities since 1991, this increase in supply will most likely be offset by other sites losing participants. Therefore, this is likely to be a substitute site for the activity and not necessarily an increase in participation rates for the activity.

TABLE 2—ESTIMATED CHANGE IN RECREATION OPPORTUNITIES IN 2016/2017

[Dollars in thousands]

Refuge	Additional days	Additional expenditures
Alamosa	499	19.4
Anahuac	350	13.6
Atchafalaya	200	7.8
Baca	970	37.8
Black Bayou Lake	200	7.8
Buffalo Lake	12	0.5
Detroit River	115	4.5
Lake Andes	0	0.0
Monte Vista	499	19.4
Montezuma	945	36.8
Patoka River	185	7.4
Waccamaw	10	0.4
Washita	60	2.3
Total	4,045	157.7

To the extent visitors spend time and money in the area of the refuge that they would not have spent there anyway, they contribute new income to the regional economy and benefit local businesses. Due to the unavailability of site-specific expenditure data, we use the national estimates from the 2011 National Survey of Fishing, Hunting, and Wildlife Associated Recreation to identify expenditures for food and lodging, transportation, and other incidental expenses. Using the average expenditures for these categories with the maximum expected additional participation of the Refuge System yields approximately $158,000 in recreation-related expenditures (Table 2). By having ripple effects throughout the economy, these direct expenditures are only part of the economic impact of these recreational activities. Using a national impact multiplier for hunting activities (2.27) derived from the report "Hunting in America: An Economic Force for Conservation" and for fishing activities (2.40) derived from the report "Sportfishing in America" yields a total economic impact of approximately $358,000 (2015 dollars) (Southwick Associates, Inc., 2012). Using a local impact multiplier would yield more accurate and smaller results. However, we employed the national impact multiplier due to the difficulty in developing local multipliers for each specific region.

Since we know that most of the fishing and hunting occurs within 100 miles of a participant's residence, then it is unlikely that most of this spending would be "new" money coming into a local economy; therefore, this spending would be offset with a decrease in some other sector of the local economy. The net gain to the local economies would be no more than $358,000, and most likely considerably less. Since 80 percent of the participants travel less than 100 miles to engage in hunting and fishing activities, their spending patterns would not add new money into the local economy and, therefore, the real impact would be on the order of about $72,000 annually.

Small businesses within the retail trade industry (such as hotels, gas stations, taxidermy shops, bait-and-tackle shops, and similar businesses) may be affected by some increased or decreased refuge visitation. A large percentage of these retail trade establishments in the local communities around NWRs qualify as small businesses (Table 3). We expect that the incremental recreational changes will be scattered, and so we do not expect that the rule will have a significant economic effect on a substantial number of small entities in any region or nationally. As noted previously, we expect approximately $158,000 to be spent in total in the refuges' local economies. The maximum increase at most would than one-tenth of 1 percent for local retail trade spending (Table 3).

TABLE 3—COMPARATIVE EXPENDITURES FOR RETAIL TRADE ASSOCIATED WITH ADDITIONAL REFUGE VISITATION FOR 2016/2017

[Thousands, 2015 dollars]

Refuge/County(ies)	Retail trade in 2012	Estimated maximum addition from new activities	Addition as % of total	Establishments in 2012	Establ. with <10 emp in 2012
Alamosa:					
Alamosa, CO	$320,858	$9.7	0.003	85	64
Costilla, CO	13,340	9.7	0.073	10	10
Anahuac:					
Chambers, TX	323,766	13.6	0.004	85	75
Atchafalaya:					
St. Martin, LA	638,981	3.9	0.001	142	101
Iberville, LA	319,242	3.9	0.001	88	61
Baca:					
Saguache, CO	26,605	37.8	0.142	16	13
Black Bayou Lake:					
Ouachita, LA	2,728,780	7.8	<0.001	710	498
Buffalo Lake:					

TABLE 3—COMPARATIVE EXPENDITURES FOR RETAIL TRADE ASSOCIATED WITH ADDITIONAL REFUGE VISITATION FOR 2016/2017—Continued

[Thousands, 2015 dollars]

Refuge/County(ies)	Retail trade in 2012	Estimated maximum addition from new activities	Addition as % of total	Establishments in 2012	Establ. with <10 emp in 2012
Randall, TX	2,063,425	0.5	<0.001	352	246
Detroit River:					
Monroe, MI	1,681,716	2.2	<0.001	377	264
Wayne, MI	19,901,061	2.2	<0.001	6,091	4,738
Monte Vista:					
Rio Grande, CO	114,102	19.4	0.017	48	41
Montezuma:					
Cayuga, NY	999,879	18.4	<0.001	260	195
Seneca, NY	559,990	18.4	<0.001	183	114
Wayne, NY	940,334	1.2	<0.001	267	181
Patoka River:					
Gibson, IN	637,370	3.7	0.001	120	84
Pike, IN	82,914	3.7	0.004	31	23
Waccamaw:					
Georgetown, SC	803,958	0.2	<0.001	303	230
Horry, SC	5,990,133	0.2	....	1,666	1,185
Washita:					
Custer, OK	606,827	2.3	<0.001	149	102

With the small change in overall spending anticipated from this proposed rule, it is unlikely that a substantial number of small entities will have more than a small impact from the spending change near the affected refuges. Therefore, we certify that, if adopted as proposed, this rule would not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). An initial regulatory flexibility analysis is not required. Accordingly, a small entity compliance guide is not required.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. We anticipate no significant employment or small business effects. This rule:

a. Would not have an annual effect on the economy of $100 million or more. The minimal impact would be scattered across the country and would most likely not be significant in any local area.

b. Would not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions. This proposed rule would have only a slight effect on the costs of hunting opportunities for Americans. If the substitute sites are farther from the participants' residences, then an increase in travel costs would occur. The Service does not have information to quantify this change in travel cost but assumes that, since most people travel less than 100 miles to hunt, the increased travel cost would be small. We do not expect this proposed rule to affect the supply or demand for hunting opportunities in the United States, and, therefore, it should not affect prices for hunting equipment and supplies, or the retailers that sell equipment.

c. Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This proposed rule represents only a small proportion of recreational spending at NWRs. Therefore, if adopted, this rule would have no measurable economic effect on the wildlife-dependent industry, which has annual sales of equipment and travel expenditures of $72 billion nationwide.

Unfunded Mandates Reform Act

Since this proposed rule would apply to public use of federally owned and managed refuges, it would not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule would not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

In accordance with E.O. 12630, this proposed rule would not have significant takings implications. This rule would affect only visitors at NWRs and describe what they can do while they are on a refuge.

Federalism (E.O. 13132)

As discussed in Regulatory Planning and Review and Unfunded Mandates Reform Act, above, this proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement under E.O. 13132. In preparing this proposed rule, we worked with State governments.

Civil Justice Reform (E.O. 12988)

In accordance with E.O. 12988, the Department of the Interior has determined that this proposed rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. The rule would clarify established regulations and result in better understanding of the regulations by refuge visitors.

Energy Supply, Distribution or Use (E.O. 13211)

On May 18, 2001, the President issued E.O. 13211 on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this proposed rule would add a new hunt at 1 NWR, increase hunting or fishing activities at 12 other NWRs, and add fishing to 1 NWR, it is not a significant regulatory action under E.O. 12866, and we do not expect it to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

In accordance with E.O. 13175, we have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects. We coordinate recreational use on NWRs with Tribal governments having adjoining or overlapping jurisdiction before we propose the regulations.

Paperwork Reduction Act

This proposed rule does not contain any information-collection requirements other than those already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and assigned OMB Control Numbers 1018–0102 (expires June 30, 2017), 1018–0140 (expires May 31, 2018), and 1018–0153 (expires December 31, 2018). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Endangered Species Act Section 7 Consultation

We comply with section 7 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), when developing Comprehensive Conservation Plans and step-down management plans—which would include hunting and/or fishing plans—for public use of refuges, and prior to implementing any new or revised public recreation program on a refuge as identified in 50 CFR 26.32. We have completed section 7 consultation on each of the affected refuges.

National Environmental Policy Act

We analyzed this proposed rule in accordance with the criteria of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)), 43 CFR part 46, and 516 Departmental Manual (DM) 8.

A categorical exclusion from NEPA documentation applies to publication of proposed amendments to refuge-specific hunting and fishing regulations because they are technical and procedural in nature, and the environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis (43 CFR 46.210 and 516 DM 8). Concerning the actions that are the subject of this proposed rulemaking, we have complied with NEPA at the project level when developing each proposal. This is consistent with the Department of the Interior instructions for compliance with NEPA where actions are covered sufficiently by an earlier environmental document (43 CFR 46.120).

Prior to the addition of a refuge to the list of areas open to hunting and fishing in 50 CFR part 32, we develop hunting and fishing plans for the affected refuges. We incorporate these proposed refuge hunting and fishing activities in the refuge Comprehensive Conservation Plan and/or other step-down management plans, pursuant to our refuge planning guidance in 602 Fish and Wildlife Service Manual (FW) 1, 3, and 4. We prepare these Comprehensive Conservation Plans and step-down plans in compliance with section 102(2)(C) of NEPA, and the Council on Environmental Quality's regulations for implementing NEPA in 40 CFR parts 1500 through 1508. We invite the affected public to participate in the review, development, and implementation of these plans. Copies of all plans and NEPA compliance are available from the refuges at the addresses provided below.

Available Information for Specific Refuges

Individual refuge headquarters have information about public use programs and conditions that apply to their specific programs and maps of their respective areas. To find out how to contact a specific refuge, contact the appropriate Regional office listed below:

Region 1—Hawaii, Idaho, Oregon, and Washington. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Eastside Federal Complex, Suite 1692, 911 NE 11th Avenue, Portland, OR 97232–4181; Telephone (503) 231–6214.

Region 2—Arizona, New Mexico, Oklahoma, and Texas. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, P.O. Box 1306, 500 Gold Avenue SW., Albuquerque, NM 87103; Telephone (505) 248–6937.

Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; Telephone (612) 713–5360.

Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the Virgin Islands. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, GA 30345; Telephone (404) 679–7166.

Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035–9589; Telephone (413) 253–8307.

Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 134 Union Blvd., Lakewood, CO 80228; Telephone (303) 236–8145.

Region 7—Alaska. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, AK 99503; Telephone (907) 786–3545.

Region 8—California and Nevada. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W–2606, Sacramento, CA 95825; Telephone (916) 414–6464.

Primary Author

Jillian Cohen, Division of Natural Resources and Conservation Planning, National Wildlife Refuge System, is the primary author of this rulemaking document.

List of Subjects in 50 CFR Part 32

Fishing, Hunting, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

Proposed Regulation Promulgation

For the reasons set forth in the preamble, we propose to amend title 50, chapter I, subchapter C of the Code of Federal Regulations as follows:

PART 32—HUNTING AND FISHING

■ 1. The authority citation for part 32 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd-668ee, and 715i.

§ 32.7 [Amended]

■ 2. Amend § 32.7 by:

■ a. Adding, in alphabetical order, an entry for "Dale Bumpers White River National Wildlife Refuge" in the State of Arkansas;

■ b. Removing the entry for "White River National Wildlife Refuge" from the State of Arkansas;

■ c. Adding, in alphabetical order, an entry for "Baca National Wildlife Refuge" in the State of Colorado;

■ d. Adding, in alphabetical order, an entry for "Billy Frank Jr. Nisqually National Wildlife Refuge" in the State of Washington; and

■ e. Removing the entry for "Nisqually National Wildlife Refuge" in the State of Washington.

■ 3. Amend § 32.20, the entry for Choctaw National Wildlife Refuge, by:

■ a. Revising paragraph B;

■ b. Revising paragraphs C.1, C.2, and C.4;

■ c. Removing paragraph C.5; and

■ d. Revising paragraphs D.2, D.4, and D.7.

The revisions read as follows:

§ 32.20 Alabama.

* * * * *

Choctaw National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of squirrel and rabbit on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit access to closed areas and hunting within 100 yards (91.4 meters) of the fenced-in refuge work center area, designated hiking trails, and refuge boat ramps.

2. We prohibit leaving unattended personal property, including, but not limited to, boats or vehicles of any type, geocaches, lumber, and cameras, overnight on the refuge (see § 27.93 of this chapter). We prohibit marking trees and using flagging tape, reflective tacks, and other similar marking devices.

3. You may take incidental species (coyote, beaver, nutria, and feral hog) during any hunt with those weapons legal during those hunts as defined by the State of Alabama. For hunting, you may possess only approved nontoxic shot (see § 32.2(k)), .22 caliber rimfire or smaller rifles, or legal archery equipment according to State regulations.

4. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

5. All persons age 15 or younger, while hunting on the refuge, must be in the presence and under direct supervision of a licensed or exempt hunter at least age 21. A licensed hunter supervising a youth must hold a valid State license for the species being hunted. One adult may supervise no more than two youth hunters.

6. The refuge is open daily from 1 hour before legal sunrise to 1 hour after legal sunset.

7. We require all hunters to record hours hunted and all harvested game on the Visitor Check-In Permit and Report (FWS Form 3–2405) at the conclusion of each day at one of the refuge check stations.

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

9. We prohibit equestrian use, domestic livestock, and use of all-terrain vehicles (ATVs) and utility-type vehicles (UTVs).

10. You must restrain all pets, except during squirrel and rabbit hunting, when you may hunt with unleashed dogs.

11. Public use information and hunting and fishing dates are available at refuge headquarters and specified in the refuge brochure.

12. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

13. We prohibit hunting with the aid of baits, salts, scent, or ingestible attractant (see § 32.2(h)).

C. * * *

1. Conditions B1 through B13 apply.

2. Deer hunters may place one portable stand or blind on the refuge for use while deer hunting, but only during the open deer season. The stand must be clearly labeled with the hunter's name, address, and phone number. You may leave the stand or blind on the refuge overnight in a non-hunting position at ground level.

* * * * *

4. We prohibit damaging trees, including driving or screwing any metal object into a tree or hunting from a tree in which a metal object has been driven or screwed to support a hunter (see § 32.2(i)).

D. * * *

2. Conditions B1, B2, B4, B6, B8 through B13, and C4 apply.

* * * * *

4. We prohibit the taking of frogs, turtles, and crawfish (see § 27.21 of this chapter).

* * * * *

7. We require a refuge Special Use Permit (FWS Form 3–1383–C) for commercial activities.

* * * * *

■ 4. Amend § 32.22, the entry for Havasu National Wildlife Refuge, by revising paragraphs A, B.2, C.1, D.3, and D.6 to read as follows:

§ 32.22 Arizona.

* * * * *

Havasu National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of mourning and white-winged dove, duck, coot, moorhen, goose, and common snipe on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit falconry.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. You may not hunt within 50 yards (45 meters) of any building or public road.

4. We prohibit target shooting.

5. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

6. We prohibit the construction or use of pits and permanent blinds (see § 27.92 of this chapter).

7. You must remove temporary blinds, boats, hunting equipment, and decoys from the refuge following each day's hunt (see §§ 27.93 and 27.94 of this chapter).

8. We prohibit retrieving game from closed areas. You may retrieve game from areas closed to hunting, but otherwise open to entry, as long as you possess no hunting firearms or other means of take.

9. Anyone hired to assist or guide hunter(s) must possess and carry a valid Special Use Permit (FWS Form 3–1383) issued by the refuge manager.

10. We prohibit hunting on those refuge lands within the Lake Havasu City limits.

11. The following conditions apply only to Pintail Slough (all refuge lands north of North Dike):

i. We require a fee for waterfowl hunting. You must possess proof of payment while hunting.

ii. Waterfowl hunters must hunt within 25 feet (7.5 meters) of the numbered post of their assigned blind.

iii. We limit the number of persons at each waterfowl hunt blind to three. Observers cannot hold shells or guns for hunting unless in possession of a valid State hunting license and stamps.

iv. We limit the number of shells a waterfowl hunter may possess to 25.

v. Waterfowl hunters must possess at least 12 decoys per blind.

vi. You may use only dead vegetation or materials brought from off refuge for making or fixing hunt blinds. We prohibit the cutting, pulling, marking or removing vegetation (see §§ 27.51 of this chapter).

vii. Waterfowl hunters must be at their blind at least 45 minutes before legal shoot time and not leave their blind until 10 a.m. MST.

viii. We allow waterfowl hunting on Wednesdays, Saturdays, and Sundays. Waterfowl hunting ends at 12 p.m. (noon) MST. Hunters must be out of the slough area by 1 p.m. MST.

ix. We allow qualifying youth to participate in the youth waterfowl hunt.

x. We allow dove hunting at Pintail Slough only during the September season.

12. The following conditions apply to all waters of the lower Colorado River within the refuge:

i. We close designated portions of Topock Marsh to all entry from October 1 through the last day of the waterfowl hunt season (including the State youth waterfowl hunt). These areas are indicated in refuge brochures and identified by buoys and/or signs.

ii. We prohibit hunting in the waters of the Colorado River and on those refuge lands within ¼ mile (.4 kilometer) of the waters of the Colorado River from and including Castle Rock Bay north to Interstate 40.

iii. We allow hunting on refuge lands and waters south of Castle Rock Bay to the north boundary of the Lake Havasu City limits.

13. We prohibit the use of all air-thrust boats and/or air-cooled propulsion engines, including floating aircraft.

14. Dogs must be under your immediate control at all times.

B. * * *

2. We prohibit the possession of rifles for hunting.

* * * * *

C. * * *

1. Conditions A2 through A9, and A12ii apply.

D. * * *

3. Anyone hired to assist or guide anglers must possess and carry a valid Special Use Permit (FWS Form 3–1383) issued by the refuge manager.

* * * * *

6. The following apply to improved areas within the refuge. Improved areas consist of the Mesquite Bay areas, Castle Rock, the Diving Cliffs, Catfish Paradise, Five Mile Landing and North Dike.

i. We prohibit entry of all motorized watercraft in all three bays of the Mesquite Bay areas as indicated by signs or regulatory buoys.

ii. Improved areas are day-use only and are open from ½ hour before legal sunrise to ½ hour after legal sunset. We allow fishing and launching water craft at these and other areas 24 hours a day.

iii. We prohibit the possession of open containers of alcohol or the possession of glass beverage containers in improved areas.

* * * * *

■ 5. Amend § 32.23 by:

■ a. Under the entry Bald Knob National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.2, A.9, A.11, and A.22;

■ ii. Revising paragraphs B.1 and B.3 through B.6;

■ iii. Revising paragraphs C.1, C.3, C.5, C.6, C.9, C.10, C.11, and C.17;

■ iv. Adding paragraph C.19; and

■ v. Revising paragraph D introductory text and paragraphs D.1 and D.2;

■ b. Under the entry Big Lake National Wildlife Refuge:

■ i. Revising paragraphs B.15, B.17, and C.7; and

■ ii. Adding paragraph C.12;

■ c. Under the entry Cache River National Wildlife Refuge:

■ i. Revising paragraphs A.2 and A.23; and

■ ii. Revising paragraph C introductory text and paragraph C.12;

■ d. Revising paragraphs B, C, and D under the entry Holla Bend National Wildlife Refuge;

■ e. Under the entry Wapanocca National Wildlife Refuge:

■ i. Revising paragraphs A.5, A.10, and A.11;

■ ii. Revising paragraph C.6; and

■ iii. Adding paragraph C.9; and

■ f. Under the entry White River National Wildlife Refuge:

■ i. Revising the heading of the entry to read, "Dale Bumpers White River National Wildlife Refuge" and moving the entry into alphabetical order within the section;

■ ii. Removing paragraph A.14;

■ iii. Redesignating paragraphs A.15 through A.26 as A.14 through A.25, respectively;

■ iv. Revising newly redesignated paragraphs A.16, A.17, A.20, and A.24;

■ v. Revising paragraphs B.1 and B.6;

■ vi. Revising paragraphs C.1, C.2, C.3, C.8, and C.10;

■ vii. Removing paragraph C.11;

■ viii. Redesignating paragraphs C.12 through C.20 as C.11 through C.19, respectively;

■ ix. Revising newly redesignated paragraphs C.18 and C.19; and

■ x. Revising paragraph D.5.

The revisions and additions read as follows:

§ 32.23 Arkansas.

* * * * *

Bald Knob National Wildlife Refuge

A. * * *

1. We require refuge hunting permits (signed brochure). The permits are nontransferable, and anyone on refuge land in possession of hunting equipment must possess a signed permit at all times.

2. We prohibit migratory game bird hunting on the refuge during the Quota Gun Deer Hunt.

* * * * *

9. We open the refuge to daylight use only, with the exception that hunters may enter the refuge beginning at 4 a.m. and must exit by 1 hour after legal shooting time ends.

* * * * *

11. You may possess only biodegradable materials to mark trails.

* * * * *

22. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, all-terrain vehicles (ATV) trails, boat ramps, observation platforms, and parking areas.

* * * * *

B. * * *

1. Conditions A1, A6, A9, A11 through A13, and A17 through A23 apply.

* * * * *

3. We allow squirrel hunting September 1 through February 28 on the Mingo Creek Unit and on the Farm Unit, except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

4. We allow rabbit hunting in accordance with the State season on the Mingo Creek Unit and on the Farm Unit, except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

5. We allow quail hunting in accordance with the State season except for season closure of the refuge during the Quota Gun Deer Hunt. We allow dogs.

6. We allow daylight hunting of raccoon and opossum with dogs on all refuge hunt units. Nighttime hunting of raccoon and opossum is allowed only on the Mingo Creek Unit with a Special Use Permit (FWS Form 3–1383–G). We require dogs for hunting raccoon/opossum at night. We list annual season dates in the refuge hunting brochure/permit. We prohibit field trials and organized training events.

* * * * *

C. * * *

1. Conditions A1, A6, A9, A11 through A13, A17 through A23, and B8 through B12 apply.

* * * * *

3. The archery/crossbow hunting season for deer begins on the opening

day of the State season and continues throughout the State season in the Mingo Creek Unit and Farm Unit except for the season closure of the refuge during the Quota Gun Deer Hunt. We provide annual season dates and bag limits in the hunt brochure/permit (signature required).

* * * * *

5. The modern gun hunting season for deer will begin in November and continue for a period of up to 9 days in all hunting units with annual season dates and bag limits provided in the hunt brochure/permit.

6. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

9. Immediately record the zone (002) on your hunting license and check all harvested game according to State regulations.

10. You may use only shotguns with rifled slugs, muzzleloaders, and legal pistols for modern gun deer hunting on the Farm Unit.

11. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them from the waterfowl sanctuaries prior to November 15, except for stands used by Quota Gun Deer Hunt permit holders (signature required), which you must remove by the last day of the Quota Gun Deer Hunt. You must remove all stands on the remainder of the refuge within 7 days of the closure of archery season (see § 27.93 of this chapter).

* * * * *

17. We allow only Quota Gun Deer Hunt permit holders on the refuge during the Quota Gun Deer Hunt and only for the purposes of deer hunting. We close the refuge to all other entry and public use during the Quota Gun Deer Hunt.

* * * * *

19. You may enter the refuge at 4 a.m. and remain until 1 hour after legal shooting time.

D. Sport Fishing. We allow fishing in accordance with State regulations subject to the following conditions:

1. Conditions A9, A11, A19 through A23, B11, and C18 apply.

2. We close waterfowl sanctuaries to all entry from November 15 to February 28. We also close the refuge to all entry and fishing during the Quota Gun Deer Hunt.

* * * * *

Big Lake National Wildlife Refuge

* * * * *

B. * * *

15. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, trails, boat ramps, parking areas, fishing piers, observation decks, and photo blinds.

* * * * *

17. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle, or boat while under power. We define "loaded" as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. * * *

7. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them 7 days before the closure of archery season (see § 27.93 of this chapter).

* * * * *

12. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

Cache River National Wildlife Refuge

A. * * *

2. We prohibit migratory game bird hunting on the refuge during the Quota Gun Deer Hunt.

* * * * *

23. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle, ATV, or boat while under power. We define "loaded" as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

12. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

Dale Bumpers White River National Wildlife Refuge

A. * * *

16. We require hunters born after 1968 to carry a valid hunter-education card. We do not require hunters under age 16 to have a hunter-education card while under direct supervision (within arm's reach) of a holder of a valid hunting license who is at least age 21. Youth hunters under age 16 must remain within sight and normal voice contact of an adult age 21 or older, possessing a valid hunting license. An adult may supervise only one youth for big game hunting but may supervise up to two youths for waterfowl and small game hunting.

17. We allow take of beaver, nutria, and coyote, incidental to any daytime refuge hunt with weapons authorized for that hunt. We prohibit take of beaver, nutria, and feral hog with the aid of dogs or after the hunter has taken the daily bag limit for that hunt. We allow feral hog to be taken during modern gun and muzzleloader deer hunts.

* * * * *

20. We allow camping only in designated sites and areas identified in the refuge user brochure/permit, and we restrict camping to individuals involved in wildlife-dependent activities. Campers may stay no more than 14 days during any 30 consecutive-day period in any campground site or area and must occupy camps daily. We prohibit all disturbances, including use of generators, after 10 p.m.

* * * * *

24. We prohibit hovercraft, personal watercraft (*e.g.,* jet skis, etc.), and airboats.

* * * * *

B. * * *

1. Conditions A1, A9, A10, A11, A12, and A15 through A25 apply.

* * * * *

6. You may possess only approved nontoxic shot when hunting upland game (see § 32.2(k)).

* * * * *

C. * * *

1. Conditions A1, A9, A10, A11, A12, and A15 through A25 apply.

2. Archery deer seasons on the North Unit are from the beginning of the State archery season until the end of January except for refuge-wide season closure during quota muzzleloader and quota gun deer hunts. We provide annual season dates and bag limits in the refuge user brochure/permit.

3. Archery deer seasons on the South Unit are from the beginning of the State archery season until the end of December except for refuge-wide season closure during quota muzzleloader and quota gun deer hunts. We provide annual season dates and bag limits in the refuge user brochure/permit.

* * * * *

8. If you harvest deer or turkey on the refuge, you must immediately record the zone number (Zone 146 South Unit and

Zone 145 North Unit) on your hunting license and later check deer and/or turkey through State phone or online checking system.

* * * * *

10. You must follow refuge guidance regarding flood-zone closures during the deer hunt. Guidance is found in the refuge brochure, which you must carry at all times.

* * * * *

18. We prohibit hunting on the Kansas Lake Area after November 30.

19. We prohibit the possession of buckshot on the refuge.

D. * * *

5. We prohibit all commercial and recreational harvest of turtle on all property administered by Dale Bumpers White River National Wildlife Refuge.

* * * * *

Holla Bend National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of squirrel, rabbit, raccoon, opossum, beaver, armadillo, coyote, and bobcat on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require refuge hunting permits (name, address, signature required). The permits are nontransferable, and anyone on refuge land in possession of hunting equipment must sign, possess, and carry the permits at all times. Your hunt permit will also act as your entrance pass to the refuge.

2. During the refuge archery season, you may take only squirrel, rabbit, raccoon, opossum, beaver, armadillo, coyote, or bobcat.

3. We allow gun hunting of raccoon and opossum with dogs every Thursday, Friday, and Saturday until legal sunrise during the month of February. We prohibit field trails and organized training events (see § 26.21(b) of this chapter).

4. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice or nonhunting discharge of firearms (see § 27.42(a) of this chapter).

5. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, boat ramps, observation platforms, and parking areas.

6. We only allow all-terrain vehicles (ATVs) for hunters and anglers with disabilities. We require a refuge ATV permit (Special Use Permit; FWS Form 3–1383–G) issued by the refuge manager.

7. We prohibit the use of horses and mules.

8. We prohibit hunting from a vehicle.

9. We only allow vehicle use on established roads and trails (see § 27.31 of this chapter).

10. You must enter and exit the refuge from designated roads and parking areas. We prohibit accessing refuge waters and land from the Arkansas River. We prohibit boating over the dam at the Old River Channel from either direction.

11. We prohibit hunting within 150 feet (45 meters) of roads open to motor vehicle use and nature trails.

12. We prohibit marking trails with tape, ribbon, paint, or any other substance other than biodegradable materials.

13. We allow the use of nonmotorized boats during the refuge fishing/boating season (March 1 to October 31), but we prohibit hunters leaving boats on the refuge overnight (see § 27.93 of this chapter).

14. You must adhere to all public use special conditions and regulations in the annual public use regulations brochure/permit.

15. You may not possess live hogs or live coyotes.

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B4 through B15 apply.

2. We allow archery/crossbow hunting for white-tailed deer and turkey. We provide annual season dates in the public use regulations brochure/permit (name, address, signature required).

3. The refuge will conduct one youth-only (between ages 6 and 15 at the beginning of the gun deer season in Zone 7) quota gun deer hunt. Specific hunt dates and application procedures will be available at the refuge office in July. We restrict hunt participants to those selected for a quota permit, except that one nonhunting adult age 21 or older must accompany the youth hunter during the youth hunt.

4. We open spring and fall archery turkey hunting during the State spring and fall turkey season for this zone.

5. We close the refuge to all entry and public use during scheduled youth quota gun hunts, except for those allowed to participate in the youth quota gun hunt.

6. The refuge will conduct two youth-only (age 6 to 15 at the beginning of the spring turkey season) quota spring gun turkey hunts, each 2 days in length. Specific hunt dates and application procedures will be available at the refuge office in January. We restrict hunt participants to those selected for a quota permit, except that one nonhunting adult age 21 or older must accompany the youth hunter during the youth hunt.

7. An adult age 21 or older must accompany and be within sight or normal voice contact of hunters age 15 and under. One adult may supervise no more than one youth hunter.

8. We allow only portable deer stands and blinds capable of being carried in their entirety by a single individual. You may erect stands 7 days before the start of the season and must remove the stands from the refuge within 7 days after the season ends (see §§ 27.93 and 27.94 of this chapter).

9. You must permanently affix the owner's name, address, and phone number to all tree stands, ground blinds, or game cameras on the refuge.

10. We prohibit the use of dogs during big game hunting.

11. We prohibit hunting from paved, graveled, and mowed roads and mowed trails (see § 27.31 of this chapter).

12. We prohibit hunting with the aid of bait, salt, or ingestible attractant (see § 32.2(h)).

13. We prohibit all forms of organized game drives.

14. You must check all game at the refuge check station.

15. We prohibit commercial hunting/guiding.

D. Sport Fishing. We allow sport fishing and frogging in accordance with State regulations and subject to the following conditions:

1. Conditions B6, B7, B9, and C5 apply.

2. Waters of the refuge are only open for fishing March 1 through October 31 during daylight hours.

3. We do not require a permit to fish but do require an entrance pass to the refuge, which can be purchased at the entrance fee station or refuge office.

4. We limit free-floating fishing devices, trotlines, and tree limb devices to 20 per person. Each device must have the angler's name and address.

5. You must reset trotlines and limb lines when receding water levels expose them.

6. We prohibit leaving trotlines and other self-fishing devices overnight or unattended.

7. You must enter and exit the refuge from designated roads and parking areas. We prohibit accessing refuge waters and land from the Arkansas River. We prohibit boating over the dam at the Old River Channel from either direction.

8. We prohibit anglers from leaving their boats unattended overnight on any portion of the refuge (see § 27.93 of this chapter).

9. We require a Special Use Permit (FWS form 3–1383–C) for all commercial fishing activities on the refuge.

10. We prohibit the take and possession of turtles and/or mollusks (see § 27.21 of this chapter).

11. We prohibit airboats, hovercraft, and personal watercraft (Jet Skis, etc.) (see § 27.31 of this chapter).

* * * * *

Wapannoca National Wildlife Refuge

A. * * *

5. We prohibit all-terrain vehicles (ATVs).

* * * * *

10. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)). We prohibit open alcohol containers on refuge roads, trails, boat ramps, parking areas, fishing piers, observation decks, and photo blinds.

11. We prohibit loaded hunting firearms or muzzleloaders in or on a vehicle or boat while under power (see § 27.42(b) of this chapter). We define "loaded" as shells in the firearm or ignition device on the muzzleloader.

* * * * *

C. * * *

6. We allow only portable deer stands capable of being carried in their entirety by a single individual. You may erect stands 7 days prior to the refuge deer season and must remove them from the waterfowl sanctuaries by December 1. You must remove all stands on the remainder of the refuge within 7 days of the closure of archery season (see § 27.93 of this chapter).

* * * * *

9. We prohibit leaving any tree stand, ground blind, or game camera on the refuge without the owner's name, address, and phone number clearly written in a conspicuous location.

* * * * *

■ 6. Amend § 32.24 by:
■ a. Under the entry Clear Lake National Wildlife Refuge:
■ i. Revising paragraphs A.1 and A.2;
■ ii. Removing paragraph A.3; and
■ iii. Revising paragraph C.1;
■ b. Revising paragraphs A.2 and A.3 under the entry Colusa National Wildlife Refuge;
■ c. Revising paragraphs A.2, A.3, and A.12 under the entry Delevan National Wildlife Refuge;
■ d. Under the entry Don Edwards San Francisco Bay National Wildlife Refuge:
■ i. Revising paragraphs A.2.iii, A.2.iv, A.3, A.4, A.5, A.6, and A.7;
■ ii. Removing paragraph A.8;
■ iii. Redesignating paragraphs A.9 and A.10 as A.8 and A.9, respectively; and
■ iv. Revising newly redesignated paragraph A.8;
■ e. Revising paragraph A.4 under the entry Lower Klamath National Wildlife Refuge;
■ f. Revising paragraphs A.2, A.3, and A.12 under the entry Sacramento National Wildlife Refuge;
■ g. Revising paragraph A under the entry Salinas National Wildlife Refuge;
■ h. Revising paragraphs A.1, A.3, A.4, A.5, A.6, and A.8 under the entry San Pablo Bay National Wildlife Refuge;
■ i. Revising paragraphs A.2 and A.3 under the entry Sutter National Wildlife Refuge; and
■ j. Under the entry Tule Lake National Wildlife Refuge:
■ i. Revising paragraph A.4;
■ ii. Redesignating paragraphs A.5 through A.9 as A.6 through A.10; and
■ iii. Adding a new paragraph A.5.

The revisions and addition read as follows:

§ 32.24 California.

* * * * *

Clear Lake National Wildlife Refuge

A. * * *

1. We allow waterfowl hunting on designated areas of the refuge 7 days per week during the State regulated season.

i. You may hunt from the shoreline only.

ii. You may not use a boat of any kind while conducting waterfowl hunting activities.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

* * * * *

C. * * *

1. You may hunt only in the unit for 9 consecutive days beginning on the first Saturday following the third Wednesday in August.

* * * * *

Colusa National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A13.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

Delevan National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A14.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

12. We prohibit snipe hunting in the assigned pond/spaced blind areas.

* * * * *

Don Edwards San Francisco Bay National Wildlife Refuge

A. * * *

2. * * *

iii. Ponds AB1, A2E, AB2, A3N, and A3W in the Alviso Unit. These ponds are located on the west side of the Bay between Stevens Creek and Guadalupe Slough. You must obtain a refuge Special Use Permit (FWS Form 3–1383) to hunt these ponds. Access to Ponds AB1 and A2E will be from the Crittenden Lane Trailhead in Mountain View. Access to Ponds A3W will be from the Carl Road Trailhead in Sunnyvale. Access to Ponds A3N and AB2 is by boat from the other ponds. We allow hunting only from existing hunting blinds. We allow hunting only on Wednesdays, Saturdays, and Sundays on these ponds.

iv. Ponds A5, A7, and A8N in the Alviso Unit. These ponds are located on the south end of the Bay between Guadalupe Slough and Alviso Slough. You must obtain a refuge Special Use Permit (FWS Form 3–1383) to hunt these ponds. Access is via walking and bicycling from the Gold Street gate in Alviso. We allow hunting from existing hunting blinds and by walking pond levees. We allow hunting only on Wednesdays, Saturdays, and Sundays on these ponds.

3. During the 2 weeks before the opening of the hunt season, you may bring a boat into Ponds AB1, A2E, AB2, A3N, A3W, A5, A7, and A8N and moor it at a designated site only if authorized by a valid refuge Special Use Permit (FWS Form 3–1383). These boats will be used to access the hunting blinds and will stay in the pond during the hunt season. You must remove your boat within 2 weeks following the close of the hunt season. We allow nonmotorized boats and motorized boats powered by electric, gasoline direct fuel injection 2-stroke, or 4-stroke gasoline motors only.

4. You may maintain an existing blind in the ponds open to hunting if you have a valid refuge Special Use Permit (FWS Form 3–1383), but the blind will be open for general use on a first-come, first-served basis. We prohibit pit blinds or digging into the levees (see § 27.92 of this chapter).

5. You must remove all decoys and other personal property (except personal boats authorized by a refuge Special Use Permit, FWS Form 3–1383) from the refuge by legal sunset. You must remove all trash, including shotshell hulls, when leaving hunting areas (see §§ 27.93 and 27.94 of this chapter).

6. You may enter closed areas of the refuge to retrieve downed birds, provided you leave all weapons in a legal hunting area. We encourage the use of retriever dogs. We prohibit other domesticated animals or pets. You must keep your dog(s) under immediate control of the handler at all times (see § 26.21(b) of this chapter). Dogs must remain inside a vehicle or be on a leash until they are on the ponds or on the levees (Ponds R1, 2, A5, 7, and 8N only) as a part of the hunt.

7. You may possess shotshells in quantities of 25 or fewer when in the field.

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

* * * * *

Lower Klamath National Wildlife Refuge

A. * * *

4. Shooting hours end at 1 p.m. on all California portions of the refuge with the following exceptions:

i. The refuge manager may designate up to 6 afternoon special youth, ladies, veteran, or disabled hunter waterfowl hunts per season.

ii. The refuge manager may designate up to 3 days per week of afternoon waterfowl hunting for the general public after December 1.

* * * * *

Sacramento National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A14.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

12. We prohibit snipe hunting in the assigned pond/spaced blind areas.

* * * * *

Salinas National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, coot, and moorhen on a hunt area along the Salinas River on the southeast portion of the refuge, as designated by posted signs, in accordance with State regulations and subject to the following conditions:

1. You may possess shotshells only in quantities of 25 or fewer.

2. Access to the hunt area is by foot traffic only. We prohibit bicycles and other conveyances. Mobility-impaired hunters should consult with the refuge manager for allowed conveyances.

3. We only allow dogs engaged in hunting activities on the refuge during the waterfowl season. You must keep dog(s) under your immediate control at all times (see § 26.21(b) of this chapter). We prohibit training of dogs on the refuge. We prohibit other domesticated animals or pets.

4. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

5. You must remove all decoys and other personal property from the refuge at the end of each day (see § 27.93 of this chapter). You must remove all trash, including shotshell hulls, when leaving hunting areas (see § 27.94 of this chapter).

* * * * *

San Pablo Bay National Wildlife Refuge

A. * * *

1. Unless posted in the field and/or noted below, we only allow hunting in the open waters of San Pablo Bay and its navigable sloughs. The following areas are closed to hunting:

i. Lower Tubbs Island;
ii. Lower Tubbs Setback;
iii. Cullinan Ranch Unit;
iv. Sonoma Baylands Unit; and
v. Within 300 feet (90 meters) of Highway 37.

* * * * *

3. You may possess shotshells only in quantities of 25 or fewer while in the field.

4. You must remove all decoys, boats, and other personal property from the refuge at the end of each day (see § 27.93 of this chapter). You must remove all trash, including shotshell hulls, when leaving hunting areas (see § 27.94 of this chapter).

5. We prohibit entry to closed areas of the refuge prior to the hunting season in order to scout for hunting sites.

6. We only allow dogs engaged in hunting activities on the refuge during waterfowl season. We prohibit other domesticated animals or pets. You must keep dog(s) under your immediate control at all times (see § 26.21(b) of this chapter). We prohibit training of dogs on the refuge.

* * * * *

8. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32). We prohibit target practice on the refuge or any nonhunting discharge of any firearm (see § 27.42 of this chapter).

* * * * *

Sutter National Wildlife Refuge

A. * * *

2. You must return the State-issued entry permit and vacate the refuge no later than 1½ hours after legal sunset unless participating in an overnight stay in accordance with A13.

3. Youth hunters must be accompanied by an adult (age 18 or older) at all times while hunting.

* * * * *

Tule Lake National Wildlife Refuge

A. * * *

4. Shooting hours end at 1 p.m. on all California portions of the refuge with the following exceptions:

i. The refuge manager may designate up to 6 afternoon special youth, ladies, veteran, or disabled hunter waterfowl hunts per season.

ii. The refuge manager may designate up to 3 days per week of afternoon waterfowl hunting for the general public after December 1.

5. You must be drawn daily to hunt all spaced blinds, including numbered blind areas, Sump 1B, and Frey's Island units, from the first day of the regulated hunting season through November 30. Drawings are held at the hunter check station located on County Road 103. Beginning December 1 through the last day of the season, spaced blinds are first-come, first-served.

* * * * *

■ 7. Amend § 32.25 by:

■ a. Revising paragraphs A, B, and C under the entry Alamosa National Wildlife Refuge;

■ b. Adding, in alphabetical order, an entry for Baca National Wildlife Refuge; and

■ c. Revising paragraphs A, B, and C under the entry Monte Vista National Refuge.

The addition and revisions read as follows:

§ 32.25 Colorado.

* * * * *

Alamosa National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of geese, ducks, coots, snipe, Eurasian collared-doves, and mourning doves on designated areas of the refuge in accordance with State and Federal regulations, and subject to the following conditions:

1. We allow Eurasian collared-dove hunting only during the mourning dove season.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

3. The only acceptable methods of take are shotguns, hand-held bows, and hawking/falconry.

4. Persons possessing, transporting, or carrying firearms on national wildlife refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

B. Upland Game Hunting. We allow hunting of cottontail rabbit, and black-tailed and white-tailed jackrabbit, on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2, A3 and A4 apply.

C. Big Game Hunting. We allow hunting of elk on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A4 applies.

2. You must possess a valid State license and a refuge-specific permit from the State, or a valid State license issued specifically for the refuge, to hunt elk. State license selection will be made via the Colorado Parks and Wildlife hunt selection process.

* * * * *

Baca National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of Eurasian collared-doves and mourning doves only in designated areas of the refuge in accordance with State and Federal regulations, and subject to the following conditions:

1. We allow Eurasian collared-dove hunting only during the mourning dove season.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

3. The only acceptable methods of take are shotguns, hand-held bows, and hawking/falconry.

4. Persons possessing, transporting, or carrying firearms on national wildlife refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

B. Upland Game Hunting. We allow hunting of cottontail rabbit, and black-tailed and white-tailed jackrabbit, on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2 and A4 apply.

2. We prohibit handguns for hunting.

3. Shotguns, rifles firing rim-fire cartridges less than .23 caliber, hand-held bows, pellet guns, slingshots, and hawking/falconry are the only acceptable methods of take.

C. Big Game Hunting. We allow hunting of elk on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A4 applies.

2. You must possess a valid State license and a refuge-specific permit from the State, or a valid State license issued specifically for the refuge, to hunt elk. State license selection will be made via the Colorado Parks and Wildlife hunt selection process.

D. Sport Fishing. [Reserved]

* * * * *

Monte Vista National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of geese, ducks, coots, snipe, Eurasian collared-doves, and mourning doves on designated areas of the refuge in accordance with State and Federal regulations, and subject to the following conditions:

1. We allow Eurasian collared-dove hunting only during the mourning dove season.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

3. The only acceptable methods of take are shotguns, hand-held bows, and hawking/falconry.

4. Persons possessing, transporting, or carrying firearms on national wildlife refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

B. Upland Game Hunting. We allow hunting of cottontail rabbit, and black-tailed and white-tailed jackrabbit, on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2, A3, and A4 apply.

C. Big Game Hunting. We allow hunting of elk on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A4 applies.

2. You must possess a valid State license and a refuge-specific permit from the State, or a valid State license issued specifically for the refuge, to hunt elk. State license selection will be made via the Colorado Parks and Wildlife hunt selection process.

3. During firearms elk seasons, hunters must follow State law for use of hunter orange.

* * * * *

■ 8. Amend § 32.27 by revising paragraph D under the entry Prime Hook National Wildlife Refuge to read as follows:

§ 32.27 Delaware.

* * * * *

Prime Hook National Wildlife Refuge

* * * * *

D. Sport Fishing. We allow fishing and crabbing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require all individuals fishing and/or crabbing on or from the refuge or within refuge waters to possess a signed refuge fishing/crabbing permit (FWS Form 3–2358) and a valid form of government-issued photo identification.

2. Anglers using boats on Turkle and Fleetwood Ponds may propel them manually or with electric motors only.

3. We do not allow fishing or crabbing from water control structures.

4. You may use or possess only nontoxic terminal tackle, weights, sinkers, and/or split shot while fishing or crabbing within refuge boundaries.

5. You may use only hook-and-line tackle when fishing for finfish.

6. You may use only hand lines, crab dip nets, hoop crab nets, and/or manually operated crab traps (collapsible traps) for crabbing.

7. You must attend to your fishing and/or crabbing lines and gear at all times.

8. We do not allow commercial fishing and/or crabbing.

* * * * *

■ 9. Amend § 32.28 by:

■ a. Revising paragraphs C and D under the entry Lake Woodruff National Wildlife Refuge;

■ b. Under the entry Merritt Island National Wildlife Refuge:

■ i. Revising paragraph A introductory text and paragraphs A.1 through A.9, A.12, A.14, and A.15;
■ ii. Adding paragraph A.16;
■ iii. Revising paragraph C;
■ iv. Revising paragraph D introductory text and paragraphs D.1, D.3, D.4, D.5, D.8, D.11, D.14, D.15, D.16, and D.17; and
■ v. Removing paragraph D.18;
■ c. Revising paragraphs C.6 through C.9 and C.12 under the entry St. Marks National Wildlife Refuge; and
■ d. Revising paragraphs C.1, C.2, C.3, C.8, C.9, C.18 and D.6 under the entry St. Vincent National Wildlife Refuge.

The addition and revisions read as follows:

§ 32.28 Florida.

* * * * *

Lake Woodruff National Wildlife Refuge

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require Lake Woodruff hunt permits. The permits (signed annual hunt brochure) are free and nontransferable, and anyone on refuge land in possession of hunting equipment must sign, possess, and carry the permit at all times.

2. In addition to the valid, paid Lake Woodruff Quota Hunt Permit (Florida Fish and Wildlife Conservation Commission State Permit), which can be purchased through Florida Fish and Wildlife Conservation Commission (FWC), and a signed Lake Woodruff National Wildlife Refuge hunt permit (signed annual hunt brochure), hunters must have on their person all applicable Florida hunting licenses and permits. State requirements for hunter safety apply.

3. All hunters must be on stands or in blinds while hunting.

4. We prohibit stalking or movement through the hunt area while hunting.

5. We prohibit scouting in the hunt area, whether you hold a permit for the current hunt or a future hunt, during the quota hunt.

6. We prohibit possession of hunting weapons while scouting.

7. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and refuge-specific regulations in this part 32).

8. We close the hunt areas of the refuge to all public use except to permitted hunters. The refuge is closed between legal sunset and legal sunrise, except permitted hunters may access the refuge 2 hours prior to legal sunrise each hunting day. All hunters must be off the refuge 2 hours after legal sunset.

9. You may set up stands or blinds 2 days prior to the hunt for which you are permitted, and you must remove them on or before the last day of your permitted hunt. You must clearly mark stands with the hunter's name and address or the Florida Fish and Wildlife Conservation Commission (FWC) customer number found on your hunting license. No more than one stand or blind per person may be on the refuge at any time, unless a permitted hunter is accompanied by a youth hunter. Stands and/or blinds for youth hunters must be placed within sight and normal voice contact of the permitted hunter's stand and marked with the adult permitted hunter's name and address or the FWC customer number and the word "YOUTH."

10. If you use flagging or other trail marking material, you must print your name or FWC customer number on each piece or marker. You may set up flagging and trail markers 2 days prior to the permitted hunt, and you must remove them on or before the last day of the permitted hunt.

11. You must check out any game taken during the hunts at a self-check station.

12. We allow primitive gun hunting only in the Western Unit, which is only accessible by boat.

13. We prohibit hunting with dogs.

14. We prohibit accessing the refuge through the railroad right-of-way.

15. Hunters under age 16 do not need a quota permit, but must be accompanied by an adult age 18 or older. Each adult may supervise one youth hunter and must remain within sight and normal voice contact; the pair must share a single bag limit unless hunting during a designated Family or Youth Hunt.

16. Archery hunters must wear a vest or jacket containing back and front panels of at least 500 square inches (3,226 square centimeters) of solid-fluorescent-orange color when moving to and from their vehicle, to their deer stand or their hunting spot, and while tracking or dragging out their deer. We do not require archery hunters to wear solid-colored-fluorescent hunter orange when positioned in their stands to hunt.

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require a Florida Freshwater Fishing license, and we adhere to State regulations for bag and length limits.

2. Fishing on the refuge is by hook and line only. We prohibit cast nets.

3. We allow fishing from legal sunrise to legal sunset.

4. We prohibit the use of airboats on the refuge.

5. We prohibit commercial fishing and the taking of frogs, turtles, or any other wildlife without permit (see § 27.21 of this chapter).

6. We prohibit the use of snatch hooks in the refuge impoundments.

* * * * *

Merritt Island National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of ducks, mergansers, and coots in designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of Federal, State, and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

2. You must possess and carry a current, signed Merritt Island National Wildlife Refuge hunt permit (signed brochure, non-transferable) at all times while hunting waterfowl on the refuge.

3. You must carry a valid State-issued Merritt Island Waterfowl Quota Permit (Waterfowl Quota Permit), which can be purchased through the Florida Fish and Wildlife Conservation Commission (FWC) while hunting in areas 1 or 4 from the beginning of the regular waterfowl season through January 31.

4. We allow hunting on Wednesdays, Saturdays, Sundays, and Federal holidays, including Thanksgiving, Christmas, and New Year's Day, that fall within the State's waterfowl season.

5. We allow hunting in four designated areas of the refuge as delineated in the refuge hunting regulations map. We prohibit hunters entering the normal or expanded restricted areas of the Kennedy Space Center (KSC).

6. We only allow hunting of waterfowl on refuge-established hunt days from ½ hour before legal sunrise until 12 p.m. (noon). All equipment must be removed by 1 p.m. daily.

7. You may enter the refuge no earlier than 4 a.m. for the purpose of waterfowl hunting.

8. You must comply with State requirements for hunter-education courses.

9. We require an adult, age 18 or older, to supervise hunters age 15 and

younger. The adult must remain within sight and normal voice contact of the youth hunter.

* * * * *

12. We prohibit hunting or shooting within 25 feet (7.6 meters), or shooting from any portion of, a dike, dirt road, or railroad grade.

* * * * *

14. You must stop at posted refuge waterfowl check stations and report statistical hunt information on the Migratory Bird Hunt Report (FWS Form 3–2361) to refuge personnel.

15. You may not possess more than 25 shells in 1 hunt day.

16. You may only use gasoline, diesel, or electric motors inside the impoundment perimeter ditch.

* * * * *

C. Big Game Hunting. We allow the hunting of white-tailed deer and feral hog in designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require a State-issued Merritt Island National Wildlife Refuge Big Game Quota Hunt Permit (Quota Hunt Permit), which can be purchased through the FWC. The Quota Hunt Permit is a limited entry quota permit, is zone-specific, and is nontransferable.

2. You must have a valid signed Big Game Hunt Permit (signed annual hunt brochure). The permits are free and nontransferable, and anyone on refuge land in possession of hunting equipment must sign and carry the signed permit at all times.

3. You must also have on your person all applicable Florida hunting licenses and permits. State requirements for hunter safety apply.

4. Licenses, permits, all hunting equipment and effects, and vehicles and/or other conveyances are subject to inspection by law-enforcement officials.

5. We allow hunting as a 3-day weekend within the State's deer season. Legal shooting hours are ½ hour before legal sunrise to ½ hour after legal sunset.

6. We close the hunt areas of the refuge to all public use except to permitted hunters.

7. The refuge is closed between legal sunset and legal sunrise except permitted hunters may access the refuge no earlier than 2 hours before legal sunrise and must leave the refuge no later than 2 hours after legal sunset.

8. You are prohibited from entering the normal or expanded restricted areas of KSC. KSC maintains the right to close any portion of the refuge for any length of time. In that case, we will not refund or reissue any permits.

9. We prohibit hunting from refuge roads or within 100 yards of roads open to public vehicle traffic or within 200 yards of a building or KSC facility.

10. Persons possessing, transporting, or carrying firearms on a National Wildlife Refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

11. Hunters under age 16 do not need a Quota Hunt Permit, but must be accompanied by an adult age 18 or older. Each adult may supervise one youth hunter and must remain within sight and normal voice contact. The pair must share a single bag limit unless hunting during a designated Youth or Family hunt.

12. You may set up stands or blinds up to 2 days prior to the permitted hunt; you must remove them on the last day of your permitted hunt. You must clearly mark stands and blinds with your name and address or the FWC customer number found on your hunting license. You may have no more than one stand or blind per person on the refuge at any time. Stands or blinds for youth hunters must be placed within sight and normal voice contact of the supervisory hunter's stand and marked with the supervisory hunter's name and address or FWC customer number and the word "YOUTH."

13. We prohibit all scouting in the hunt area during the quota hunt.

14. If you use flagging or other trail-marking material, you must print your name or FWC customer number on each piece or marker. You may set out flagging and trail markers up to 2 days prior to the permitted hunt, and you must remove them on the last day of the permitted hunt.

15. We allow legally permitted hunters to scout within their permitted zones up to 7 days prior to their permitted hunts. You must carry your valid Quota Hunt Permit identifying the permitted hunt zone while scouting.

16. We allow parking for scouting and/or hunting only along State Road (SR) 3, not within the hunt areas.

17. You must be on your stand or in your blind while hunting.

18. We prohibit stalking or moving through the hunt area while hunting.

19. You must be at your vehicle within 1 hour after legal shooting time. If you wish to track wounded game beyond 1 hour after legal sunset, you must gain consent from a Federal Wildlife Officer to do so.

20. We prohibit hunting with dogs.

21. We prohibit using dogs for tracking unless authorized by a Federal Wildlife Officer. Dogs must remain on a leash and be equipped with a GPS tracking device.

22. You may field dress game; however, we prohibit cleaning game within 1,000 feet of any public area, road, game-check station, or gate. We prohibit dumping game carcasses on the refuge.

23. Archery hunters must wear at least 500 square inches (3,226 square centimeters) of solid fluorescent-orange color while moving to and from their vehicles, to their stands or hunting spots, and while tracking or dragging out game.

24. The bag limit and antler requirements for white-tailed deer on the refuge will follow State regulations but will not exceed two deer per hunt. Antlered and antlerless deer are defined per State regulations. It is illegal to take spotted fawns.

25. There is no bag limit or size limit for the take of feral hogs.

26. You must report all hunting activities at one of the two check stations, including both successful and non-successful hunts, prior to leaving the refuge.

D. Sport Fishing. We allow recreational fishing, crabbing, clamming, and shrimping in designated areas of the refuge as delineated in the refuge fishing regulations map in accordance with State regulations and subject to the following conditions:

1. You must possess a current, signed refuge fishing permit (signed brochure) and a Florida State Freshwater and/or Saltwater fishing license at all times while fishing on the refuge. All State regulations for bag and length limits apply.

* * * * *

3. We allow launching of boats for night fishing activities only from Bair's Cove, Beacon 42, and Biolab boat ramps.

4. We prohibit crabbing or fishing from Black Point Wildlife Drive or any side road connected to Black Point Wildlife Drive except from L Pond Road.

5. We prohibit launching boats, canoes, or kayaks from Black Point Wildlife Drive or any side road connected to Black Point Wildlife Drive except from L Pond Road.

* * * * *

8. We prohibit use of personal watercraft, kite surfing, kite boarding, wind surfing, sail boarding, use of air thrust boats, and use of hovercraft or any similar non-wildlife oriented watercraft on the refuge or in refuge waters.

* * * * *

11. We prohibit fishing within the normal or expanded restricted areas of

the KSC, unless those areas are officially designated by KSC as special fishing opportunity sites.

* * * * *

14. We prohibit fishing from, or in the immediate vicinity of, the Manatee Viewing Deck on the northeast side of Haulover Canal.

15. We require all commercial fishing guides to purchase, possess, and carry a Special Use Permit (FWS Form 3–1383–C).

16. You may only use gasoline, diesel, or electric motors inside the impoundment perimeter ditch.

17. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of Federal, State, and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and this part 32).

* * * * *

St. Marks National Wildlife Refuge

* * * * *

C. * * *

6. There are two fall archery hunts: You may harvest either-sex deer, feral hog, and bearded turkey during the fall archery hunts. We will hold one hunt on the Panacea Unit and one hunt on the Wakulla Unit. See condition C8 for specific information on bag limits. Contact the refuge office for specific dates.

7. There are two modern gun hunts. You may harvest deer, feral hog, and bearded turkey. Modern guns must meet State requirements. We will hold one hunt on the Panacea Unit and one hunt on the Wakulla Unit. See condition C8 for specific information on bag limits. Contact the refuge office for specific dates.

8. The bag limit for white-tailed deer is two deer per hunt, either two antlerless deer or one antlerless deer and one antlered deer. Antlerless deer are defined per State regulations as deer with no antler or antlers less than 5 inches (12.75 centimeters). Antlered deer must have at least three points, 1 inch (2.5 centimeters) or greater on one antler to be harvested.

9. There is one youth white-tailed deer hunt and one youth turkey hunt for youth ages 12 to 17, on the St. Marks Unit in an area we will specify in the refuge hunt brochure. Youth hunters age 12 to 15 may harvest two deer, either two antlerless deer or one antlerless and one antlered. There are no restrictions on antler size for youth age 12 to 15. Youth hunters age 16 to 17 may harvest two deer, either two antlerless or one antlerless and one antlered. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or greater on one antler to be harvested by youth age 16 to 17. Antlerless deer are defined in C8. The youth turkey hunt will be conducted in the St. Marks Unit in an area we will specify in the refuge hunt brochure. The limit will be one bearded turkey per hunter. Unlimited hogs may be harvested on both hunts. Only the youth hunter may handle or discharge firearms used for hunting. An adult age 21 or older must accompany and remain in sight and normal voice contact with each youth hunter. Contact the refuge office for specific dates.

* * * * *

12. Portions of the St. Marks Unit adjacent to Flint Rock Wildlife Management Area (as specified in the hunt brochure) will be open concurrent with Flint Rock Wildlife Management Area seasons and regulations except only white-tailed deer, feral hog, and turkey may be harvested. We require a refuge permit (signed brochure).

* * * * *

St. Vincent National Wildlife Refuge

* * * * *

C. * * *

1. We require refuge permits (State license—fee charged). The permits are nontransferable, and the hunter must possess them while hunting. Only signed permits are valid. We only allow people with a signed refuge hunt permit or the helpers of mobility-impaired hunters on the island during the hunt periods. Contact the refuge office for details on receiving a permit. We will charge fees for duplicate permits.

2. We restrict hunting to three periods: Primitive Weapons Sambar Deer (sambar deer, raccoon, and feral hog); Archery (white-tailed deer, raccoon, feral hog); and Primitive Weapons White-Tailed Deer (white-tailed deer, raccoon, and feral hog). Contact the refuge office for specific dates. You may check-in and set up camp sites and stands on the day prior to the scheduled hunt as specified in the brochure. You must leave the island and remove all equipment by the date and time specified in the brochure.

3. You must check-in at the check stations on the island. We restrict entry onto St. Vincent Island to the Indian Pass and West Pass Campsites. All access to hunt areas will be on foot or by bicycle from these areas.

* * * * *

8. You may retrieve game from the closed areas only if accompanied by a refuge staff member or a Federal Wildlife Officer.

9. We limit weapons to primitive weapons (bow and arrow and muzzleloader) on the primitive weapons sambar deer hunt and the primitive weapons white-tailed deer hunt. We limit the archery hunt to bow and arrow. Weapons must meet all State regulations. We prohibit crossbows during the white-tailed deer archery hunt except with a State disabled persons permit. You may take feral hog and raccoon only with the weapons allowed for that period.

* * * * *

18. Bag limits:

i. Primitive Weapons Sambar Deer Hunt: One sambar deer of either sex, no limit on feral hog or raccoon.

ii. Archery Hunt: One white-tailed deer of either sex. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or more on one antler to be harvested. Antlerless deer are defined per State regulations as deer with no antler or antlers less than 5 inches (12.75 centimeters). Youth age 15 or younger may harvest any deer except spotted fawn. We prohibit harvesting of spotted fawns. There is no limit on feral hog or raccoon.

iii. Primitive Weapons White-Tailed Deer Hunt: One white-tailed deer. Antlered deer must have at least two points, 1 inch (2.5 centimeters) or more in length on one antler, to be harvested. We issue a limited number of either-sex tags. If you have an either-sex tag, the bag limit is one deer that may be antlerless or antlered with legal antler configuration. Antlerless deer are defined per State regulation as deer with no antler or antlers less than 5 inches (12.75 centimeters). Youth age 15 or younger may harvest any deer except spotted fawn. We prohibit harvesting of spotted fawns. There is no limit on feral hog or raccoon.

* * * * *

D. * * *

6. You may take only fish species, and you must comply with the fish limits, authorized by State regulations. We prohibit the taking of frog and/or turtle.

■ 10. Amend § 32.31 by:

■ a. Revising paragraphs A, C.2, C.7, C.8, D.1, and D.4 under the entry Deer Flat National Wildlife Refuge; and

■ b. Revising paragraph A introductory text and paragraphs A.4 and C under the entry for Kootenai National Wildlife Refuge.

The revisions read as follows:

§ 32.31 Idaho.

* * * * *

Deer Flat National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, coot, common snipe, and dove on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You may hunt only duck, coot, and mourning dove on the Lake Lowell Unit.

2. You may hunt duck and coot only within 200 yards (180 meters) of the shoreline.

3. Duck and coot hunting in the East Side Recreation Area is walk-in only. We prohibit using float tubes and boats. Duck and coot hunters in the South Side Recreation Area may use float tubes, nonmotorized boats, or boats equipped with electric motors within 200 yards (180 meters) of the shoreline. We prohibit the use or possession of gas-powered motors.

4. You may possess only 25 or fewer shotgun shells per day for hunting duck and coot.

5. You may only use portable and temporary blinds. We prohibit permanent structures (see § 27.92 of this chapter).

6. You must remove boats, decoys, blinds, other personal property, and any materials brought onto the refuge for blind construction at the end of each day (see §§ 27.93 and 27.94 of this chapter).

7. You may enter the refuge 1 hour before official shooting hours (1/2 hour before legal sunrise), and remain on the refuge until 1 hour after official shooting hours (legal sunset).

8. You may use dogs for hunting. Dogs must be under the immediate control of the handler at all times.

9. From February 1 through June 14, we prohibit hunting on all islands in the Snake River Islands Unit. From June 15 through June 30, we prohibit hunting on islands used by nesting birds. You must comply with all posted signs.

* * * * *

C. * * *

2. Only the southern portion of the Lake Lowell Unit is open to deer hunting. We define the boundary of the deer hunting area on the north by the southern shoreline of Lake Lowell, on the east by the New York Canal, on the south by the southern boundary of the refuge, and on the west by Riverside Road.

* * * * *

7. You may enter the Lake Lowell Unit no earlier than 2 hours before official shooting hours (1/2 hour before legal sunrise) and must leave the area within 2 hours after official shooting hours (1/2 hour after legal sunset). Successful hunters may extend their departure time only as long as is necessary to retrieve dead deer.

8. A refuge employee, State Game Warden, or local law-enforcement officer must accompany hunters to retrieve a wounded or dead deer from any area that is closed to deer hunting.

D. * * *

1. From October 1 through April 14, we only allow ice fishing within 200 yards (180 meters) of the shoreline in front of both the Lower Dam (Fishing Area A) and the Upper Dam (Fishing Area B) on the Lake Lowell Unit, unless otherwise posted by the Bureau of Reclamation.

* * * * *

4. From February 1 through June 14, we prohibit fishing from all islands in the Snake River Islands Unit. From June 15 through June 30, we prohibit fishing from islands used by nesting birds. You must comply with all posted signs.

* * * * *

Kootenai National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of goose, duck, and coot on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

4. On waterfowl hunt days, we allow waterfowl hunters to access the waterfowl hunt area after 3 a.m.

* * * * *

C. Big Game Hunting. We allow hunting of deer, elk, black bear, moose, and mountain lion on that portion of the refuge that lies west of Lion's Den Road in accordance with State regulations and subject to the following conditions:

1. We allow hunting of white-tailed deer at the designated accessible blind for hunters with disabilities subject to the following conditions:

i. You may only participate in deer hunting at the accessible blind with a refuge permit (name/address/phone number), which is issued through a random drawing in early August. You may apply for a 7-day archery-only permit (name/address/phone number) or a 7-day archery/special weapons-only permit (name/address/phone number). A total of 4 weeks of archery-only permits and 6 weeks of archery/special weapon-only permits will be available.

ii. You must possess a valid State disabled hunting license and tag and provide proof of this prior to the drawing.

iii. We only allow deer hunting at the accessible blind using the following weapons: Muzzleloader, archery equipment, crossbow, shotgun, or handgun. For shotguns, you may only use slugs. For handguns, you may only use straight-walled cartridges not originally established for rifles.

iv. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

2. We prohibit the use of dogs to hunt big game.

* * * * *

■ 11. Amend § 32.32 by:

■ a. Under the entry Crab Orchard National Wildlife Refuge:

■ i. Removing paragraph B.6;

■ ii. Redesignating paragraphs B.3 through B.5 as B.4 through B.6, respectively;

■ iii. Adding a new paragraph B.3; and

■ iv. Revising paragraphs C.3. and D.10;

■ b. Under the entry Great River National Wildlife Refuge:

■ i. Revising paragraph C.5; and

■ ii. Removing paragraph C.7.iii;

■ c. Revising paragraphs B.1, C.1, C.2, and D.4 under the entry Middle Mississippi River National Wildlife Refuge; and

■ d. Under the entry Port Louisa National Wildlife Refuge:

■ i. Adding an introductory sentence immediately after the entry's heading and before paragraph A; and

■ ii. Revising paragraphs B.2 through B.5.

The revisions and additions read as follows:

§ 32.32 Illinois.

* * * * *

Crab Orchard National Wildlife Refuge

* * * * *

B. * * *

3. For hunting, you may possess only approved nontoxic shot shells while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)).

* * * * *

C. * * *

3. We allow the use of legal-sized lead ammunition (see current Illinois hunting digest) for the taking of deer.

* * * * *

D. * * *

10. Anglers may not submerge any poles or similar object to take or locate any fish.

* * * * *

Great River National Wildlife Refuge

* * * * *

C. * * *

5. On the Fox Island Division, we only allow deer hunting during the Statewide archery deer season and special managed hunts.

* * * * *

Middle Mississippi River National Wildlife Refuge

* * * * *

B. * * *

1. On the Wilkinson Island Division, you must comply with both Illinois and Missouri firearm blaze-orange safety

requirements from October 1 to January 31.

* * * * *

C. * * *

1. Conditions A1, A2, and B1 apply. Condition A4 applies only to wild turkey.

2. On the Harlow, Crains, and Meissner Island Divisions, you may only use archery equipment to harvest white-tailed deer.

* * * * *

D. * * *

4. You must remove all fishing devices (see § 27.93 of this chapter) at the end of each day's fishing.

* * * * *

Port Louisa National Wildlife Refuge

Refer to § 32.34 (Iowa) for regulations regarding Iowa River Corridor Lands.

* * * * *

B. * * *

2. Condition A3 applies to upland game, including wild turkey. We allow shotgun slug or muzzleloading rifle for hunting coyotes.

3. We allow only squirrel hunting on the Keithsburg Division from the beginning of the State season to September 15. We prohibit hunting of any other upland game on the Keithsburg Division.

4. We allow hunting on the Horseshoe Bend Division from September 1 until September 15, and December 1 until February 28. We allow spring turkey hunting.

5. We allow hunting on the Big Timber Division from September 1 until February 28. We allow spring turkey hunting.

* * * * *

■ 12. Amend § 32.33, the entry for Patoka River National Wildlife Refuge and Management Area, by:

■ a. Adding paragraph A.9; and

■ b. Revising paragraphs B.1, B.3, and C.6.

The addition and revisions read as follows:

§ 32.33 Indiana.

* * * * *

Patoka River National Wildlife Refuge and Management Area

A. * * *

9. We prohibit the use of trail and game cameras on the refuge.

B. * * *

1. You must register to hunt furbearers at the refuge office, record the number of furbearers harvested on the Upland Game Hunt Report (FWS Form 3–2362), and return the completed form to the refuge office after the hunting season.

* * * * *

3. Conditions A7 through A9 apply.

C. * * *

6. Conditions A6 through A9 apply. Condition A8 applies only to wild turkey.

* * * * *

■ 13. Amend § 32.34 by:

■ a. Revising the entry for Iowa Wetland Management District; and

■ b. Adding an introductory sentence immediately after the entry's heading and before paragraph A under Port Louisa National Wildlife Refuge.

The addition and revision read as follows:

§ 32.34 Iowa.

* * * * *

Iowa Wetland Management District

A. Migratory Game Bird Hunting. We allow hunting of migratory game birds throughout the district in accordance with State regulations and subject to the following conditions:

1. For hunting, you may possess only approved nontoxic shot shells while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)).

2. We prohibit leaving boats, decoys, or other personal property unattended at any time. You must remove all personal property, which includes boats, decoys, and blinds, brought onto the district at the end of each day (see §§ 27.93 and 27.94 of this chapter).

3. We allow boats or other floating devices. We restrict all watercraft motors to 15 horsepower (11.2 kW) or less.

B. Upland Game Hunting. We allow upland game hunting throughout the district in accordance with State regulations and subject to the following condition: Conditions A1 and A2 apply.

C. Big Game Hunting. We allow big game hunting throughout the district in accordance with State regulations and subject to the following conditions:

1. You may leave tree stands in an area for a continuous period of time beginning 7 days prior to the open season for hunting deer and ending 7 days after the final day of that season. You must clearly mark the stand with your name or Iowa hunting license number.

2. You do not have exclusive use of the tree stand when unattended or exclusive use of the tree stand site.

3. We prohibit driving nails, screws, spikes, or other metal objects into a tree (see § 32.2(i)).

D. Sport Fishing. We allow sport fishing throughout the district in accordance with State regulations and subject to the following conditions:

1. Condition A3 applies.

2. You must remove all ice fishing shelters and other personal property at the end of each day's fishing (see § 27.93 of this chapter).

* * * * *

Port Louisa National Wildlife Refuge

Refer to § 32.32 (Illinois) for Port Louisa National Wildlife Refuge fee title lands.

* * * * *

■ 14. Amend § 32.35 by:

■ a. Under the entry Flint Hills National Wildlife Refuge:

■ i. Redesignating paragraphs A.1 through A.9 as A.2 through A.10, respectively;

■ ii. Adding a new paragraph A.1;

■ iii. Revising newly redesignated paragraph A.10;

■ iv. Revising paragraphs B.1 and C.6; and

■ v. Adding paragraph C.7;

■ b. Under the entry Kirwin National Wildlife Refuge:

■ i. Removing paragraph A.8;

■ ii. Redesignating paragraphs A.9 through A.12 as A.8 through A.11, respectively;

■ iii. Removing paragraph B.3;

■ iv. Redesignating paragraphs B.4 through B.6 as B.3 through B.5, respectively;

■ v. Revising newly redesignated paragraph B.5; and

■ vi. Revising paragraphs C.9 and D.9; and

■ c. Under the entry Marais des Cygnes National Wildlife Refuge:

■ i. Redesignating paragraphs A.1 through A.4 as A.2 through A.5, respectively;

■ ii. Adding a new paragraph A.1;

■ iii. Revising paragraphs B.1, B.4, and C.1;

■ iv. Adding paragraphs C.4 and C.5; and

■ v. Revising paragraph D.

The revisions and additions read as follows:

§ 32.35 Kansas.

* * * * *

Flint Hills National Wildlife Refuge

A. * * *

1. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

* * * * *

10. We allow crow hunting on designated areas of the refuge subject to the following conditions:

i. We prohibit the use of centerfire rifles and pistols for hunting on the refuge.

ii. We close hunting areas on the north side of the Neosho River to all hunting from November 1 through March 1.

iii. Conditions A1, A3, A4, A7, and A8 apply.

B. * * *

1. Conditions A1, A3, A7, and A8 apply.

* * * * *

C. * * *

6. We prohibit the use of electronic or photographic trail-monitoring devices.

7. Conditions A1, A3, A7, A8, B3 and B4 apply.

* * * * *

Kirwin National Wildlife Refuge

* * * * *

B. * * *

5. Conditions A1, A8, A9, A10, and A11 apply.

C. * * *

9. Conditions A8 through A11 apply.

D. * * *

9. Conditions A8 through A11 apply.

Marais des Cygnes National Wildlife Refuge

A. * * *

1. You must possess and carry a signed refuge hunt permit (signed brochure) when hunting.

* * * * *

B. * * *

1. Conditions A1 and A3 apply.

* * * * *

4. You may possess only approved nontoxic shot for hunting (see § 32.2(k)).

C. * * *

1. Conditions A1, A3, A4, A5, and B2 apply.

* * * * *

4. We prohibit the use of electronic or photographic trail monitoring devices.

5. You may possess only approved nontoxic shot for turkey hunting (see § 32.2(k)).

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following condition: Condition A2 applies.

* * * * *

■ 15. Amend § 32.36, the entry for Clarks River National Wildlife Refuge, by:

■ a. Revising paragraphs A.5, A.6, A.9, A.12, A.17, A.18, and A.19;

■ b. Removing paragraph A.20; and

■ c. Revising paragraphs C.2 and C.5.

The revisions read as follows:

§ 32.36 Kentucky.

* * * * *

Clarks River National Wildlife Refuge

A. * * *

5. You must possess and carry a signed refuge permit (signed brochure) while hunting and/or fishing on the refuge.

6. To retrieve or track game from a posted closed area of the refuge, you must first receive authorization from the refuge manager at 270–527–5770 or the law enforcement officer at 270–703–2836.

* * * * *

9. We prohibit discharge of firearms on or within 200 feet (90 meters) of any home, the abandoned railroad tracks, graveled roads, and hiking trails.

* * * * *

12. We allow trail cameras. Cameras may be used year-round. Cameras must have the owner's name, address, and phone number clearly displayed or they may be confiscated.

* * * * *

17. By 12 p.m. (noon) during the Statewide waterfowl season: You must cease hunting; unload firearms used for waterfowl hunting (see § 27.42(b) of this chapter); remove decoys, blinds, boats, and all other equipment (see § 27.93 of this chapter); and be out of the field daily.

18. We close to all entry of, as posted, the Clarks River Waterfowl Units from November 1 through March 31, with the exception of drawn permit holders (name/address/phone) and their guests.

19. We only allow waterfowl hunting on the Clarks River Waterfowl Units on specified days during the State waterfowl season. We only allow hunting by individuals in possession of a drawn permit and their guests. State regulations and the following conditions apply:

i. Application procedures and eligibility requirements are available from the refuge office.

ii. We allow drawn permit holders and up to four guests to hunt their assigned zone and/or provided blind on the designated date. We prohibit guests on the Clarks River Waterfowl Units without the attendance of the drawn permit holder.

iii. We prohibit selling, trading, or bartering of drawn permits. These permits are nontransferable.

iv. You may place decoys out the first morning of the drawn hunt, and you must remove them at the close of the drawn hunt (see § 27.93 of this chapter).

v. We prohibit watercraft on the Clarks River Waterfowl Units, except for drawn permit holders to access their blinds and retrieve downed birds as needed.

* * * * *

C. * * *

2. We only allow the use of portable and climbing stands. You may place stands in the field no earlier than 2 weeks prior to the opening of deer season, and you must remove them from the field within 1 week after the season closes (see §§ 27.93 and 27.94 of this chapter). The hunter's name, address, and phone number must appear on all stands left in the field.

* * * * *

5. Ground blinds used for the purpose of hunting any species during the deer modern gun, muzzleloader, and youth firearms seasons must display one square foot (144 square inches) of solid, unbroken, hunter orange visible from all sides. You must remove ground blinds when not in use.

* * * * *

■ 16. Amend § 32.37 by:

■ a. Revising the entry for Atchafalaya National Wildlife Refuge;

■ b. Under the entry Bayou Cocodrie National Wildlife Refuge:

■ i. Revising paragraph A;

■ ii. Revising paragraphs B.3, B.5, and B.6;

■ iii. Revising paragraphs C.2, C.3, C.4, and C.5;

■ iv. Redesignating C.11 and C.12 as C.12 and C.13, respectively;

■ v. Adding a new paragraph C.11;

■ vi. Revising newly redesignated paragraph C.13; and

■ vii. Revising paragraph D;

■ c. Revising paragraph C.1 under the entry Bayou Teche National Wildlife Refuge;

■ d. Revising paragraphs A.15 and B.1 under the entry Big Branch Marsh National Wildlife Refuge;

■ e. Under the entry Black Bayou Lake National Wildlife Refuge:

■ i. Revising paragraphs A, B, and C;

■ ii. Removing paragraph D.8; and

■ iii. Redesignating paragraph D.9 as D.8;

■ f. Revising paragraphs A.7, A.11, and C.8 under the entry Bogue Chitto National Wildlife Refuge;

■ g. Under the entry Cat Island National Wildlife Refuge:

■ i. Revising paragraphs A, B.3, C.3, C.4, C.7, and C.8;

■ ii. Redesignating paragraph C.9 and C.10 as C.10 and C.11, respectively;

■ iii. Adding a new paragraph C.9; and

■ iv. Revising paragraph D.8;

■ h. Revising paragraphs A, B, C, D.1, and D.3 under the entry D'Arbonne National Wildlife Refuge; and

■ i. Revising paragraphs A, B, C, D.2, and D.4 under the entry Upper Ouachita National Wildlife Refuge.

The additions and revisions read as follows:

§ 32.37 Louisiana.

* * * * *

Atchafalaya National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory game birds on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Hunting must be in accordance with State-issued Sherburne Wildlife Management Area regulations.

2. Feral hogs are incidental take species. You may take feral hog during any open hunting season, only with the weapon allowed for that season, and only if you are a hunter with proper licenses and permits for that season. There is no bag limit on feral hog.

B. Upland Game Hunting. We allow hunting of upland game on designated areas of the refuge in accordance with State regulations and subject to the following conditions: A1 and A2 apply.

C. Big Game Hunting. We allow hunting of white-tailed deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions: A1 and A2 apply.

D. Sport Fishing. We allow finfishing and shellfishing year-round in accordance with Sherburne Wildlife Management Area regulations and subject to the following condition: We prohibit all commercial finfishing and shellfishing without a Special Use Permit (FWS Form 3–1383–C).

Bayou Cocodrie National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, coot, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We require that all hunters and anglers age 16 and older purchase an annual public use permit (name/address/telephone number). We waive the fee for individuals age 60 and older. You must sign the permit, certifying that you understand and will comply with all regulations. You must carry this permit at all times while on the refuge.

2. We allow migratory game bird hunting on Wednesdays, Saturdays, and Sundays until 12 p.m. (noon) during the State season. We do not open for the special teal season or the State youth waterfowl hunt.

3. We prohibit hunting within 150 feet (45 meters) of the maintained rights-of-way of roads, refuge roads or designated trails, buildings, residences, or designated public facilities.

4. You must remove harvested waterfowl, temporary blinds, and decoys (see § 27.93 of this chapter) used for duck hunting by 1 p.m. daily.

5. We only allow dogs to locate, point, and retrieve when hunting for migratory game birds.

6. While hunting, all persons age 16 or younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

7. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

8. We prohibit use or possession of any type of trail-marking material.

9. Coyote, beaver, feral hog, and raccoon are incidental take species and you may take them during any open hunting season only with the weapon allowed for that season if you are a hunter having the required licenses and permits. There is no bag limit on coyote, feral hog, and beaver. State regulations apply on other incidental species.

10. You must check all game taken on the refuge before leaving the refuge at one of the self-clearing check stations indicated on the map in the refuge Hunting and Fishing Regulations Brochure.

11. We allow all-terrain vehicles (ATVs) and utility vehicles in accordance with State Wildlife Management Area (WMA) regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches (66 cm) by 12 inches (30.5 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

12. You may possess only approved nontoxic shot while hunting on the refuge (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

13. You must obtain a daily use reporting card (one per person) and place it on the dashboard of your vehicle or in your boat so that your personal information (name/city/State/zip code) is readable and in plain view. You must complete all the information requested (name/address/phone number) and return the cards to the refuge kiosk/check stations upon departure from the refuge.

14. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset except that raccoon and opossum hunters during the month of February may use the refuge at night.

15. Waterfowl hunters are allowed no more than 25 shotshells per person.

B. * * *

3. We allow the use of dogs to hunt squirrel and rabbit during that portion of the season designated as small game with dogs. We list specific season dates in the refuge brochure.

* * * * *

5. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset.

6. While hunting, all persons age 16 and younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

C. * * *

2. The bag limit is one deer per day. The State tagging regulations apply.

3. You must check all deer on the same day taken during lottery deer hunts at the nearest refuge check station.

4. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken hunter orange. You must wear the solid-hunter-orange items while in the field.

5. You may place stands up to 2 days prior to established hunting season dates. You must remove stands by 2 days after the hunting season closes. You must mark your name and phone number on your stand. You are allowed one portable stand or blind on the refuge.

* * * * *

11. We prohibit the use of trail cameras.

* * * * *

13. There is an application fee per person for the lottery gun hunt application (name/address/phone number). We waive the fee for youth and special access applications.

D. Sport Fishing. We allow fishing on the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A11 through A15 apply.

2. We prohibit commercial fishing.

3. We prohibit the taking of alligator snapping turtle (see § 27.21 of this chapter).

4. We only allow fishing during daylight hours.

5. The refuge boat ramp is open for daylight use only, except during specified hunting seasons when the ramp is open from 4 a.m. until 2 hours after legal sunset.

6. We prohibit wire traps, slat traps, wire nets, hoop nets, trotlines, yo-yos, and jug lines on the refuge.

* * * * *

Bayou Teche National Wildlife Refuge

* * * * *

C. * * *

1. We allow hunting of deer only with firearms (see § 27.42 of this chapter) during 5 specific days during October and November. A youth gun hunt will occur during the last weekend of October. The general gun hunt will occur during the final full weekend in November. The youth gun hunt includes both Saturday and Sunday. The general gun hunt includes the Friday immediately before the weekend.

* * * * *

Big Branch Marsh National Wildlife Refuge

A. * * *

15. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs).

* * * * *

B. * * *

1. We allow upland game hunting during the open State season. When hunting, you may possess only approved nontoxic shot (see § 32.2(k) of this chapter), shot size 4 or smaller, or 0.22 caliber rimfire rifles or smaller.

* * * * *

Black Bayou Lake National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. We prohibit accessing the hunting area by boat from Black Bayou Lake.

5. You may enter the refuge no earlier than 4 a.m.

6. We prohibit hunting within 100 feet (30 meters) of the maintained right-of-way of roads and from or across all-terrain vehicle (ATV) trails (see § 27.31 of this chapter). We prohibit hunting within 50 feet (15 meters), or trespassing on above-ground oil, gas, or electrical transmission facilities.

7. We prohibit leaving boats, blinds, and decoys overnight.

8. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

9. Youths are generally defined as those individuals age 17 or younger, except that for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

10. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

11. We only allow ATVs on trails (see § 27.31 of this chapter) designated for their use and marked by signs. ATV trails are closed March 1 through August 31. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 lbs. (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 25 inches by 12 inches (62.5 cm by 30 cm) with a maximum of 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge as indicated in the annual Public Use Regulations brochure and in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A4, A6, A9, A10, and A11 apply.

2. Specific open dates and open areas to small game hunting will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 1 hour after legal shooting hours end.

5. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting on the refuge. This requirement only applies to the use of shotgun ammunition.

C. Big Game Hunting. We allow archery hunting of white-tailed deer on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A4, A6, A9, A10, A11, and B4 apply.

2. Specific open dates and open areas will appear in the annual Public Use Regulations brochure.

3. We prohibit gun deer hunting.

4. The daily bag limit is one deer of either sex. The State season limit applies.

5. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

6. An adult at least age 21 must supervise youth hunters under age 16 during all hunts. One adult may supervise two youths during small game and migratory bird hunts but may supervise only one youth during big game hunts. Youth must remain within normal voice contact of the adult who is supervising them. Parents or adult guardians are responsible for ensuring that hunters under age 16 do not violate refuge regulations.

7. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or any nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

* * * * *

Bogue Chitto National Wildlife Refuge

A. * * *

7. We prohibit hunting within 150 feet (45 meters) from the centerline of any public road, refuge road, designated or maintained trail, building, residence, designated public facility, or from or across aboveground oil or gas or electric facilities. We prohibit hunting in refuge-designated closed areas, which we post on the refuge and identify in the refuge hunt permits (signed brochure).

* * * * *

11. We prohibit horses, trail cameras, all-terrain vehicles (ATVs), and utility-type vehicles (UTVs).

* * * * *

C. * * *

8. You may take hog as incidental game while participating in the refuge archery, primitive weapon, and general gun deer hunts and where otherwise specified. We list specific dates for the special hog hunts in January, February, and March in the refuge hunt permit (signed brochure). During the special hog hunts in February, you must use trained hog-hunting dogs to aid in the take of hog. During the special hog hunts, you may take hog from ½ hour before legal sunrise until ½ hour after legal sunset. You may possess only approved nontoxic shot or pistol or rifle ammunition not larger than .22 caliber rimfire to take the hog after it has been caught by dogs. During the special hog hunt in March, you may use any legal firearm. A8 applies during special hog hunts in February.

* * * * *

Cat Island National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, coot, and woodcock on designated areas of the refuge as shown on the refuge hunt brochure map in accordance with State regulations and subject to the following conditions:

1. We require that all hunters and anglers age 16 and older purchase an annual public use permit (name/address/telephone number). We waive the fee for hunters age 65 and older. The refuge user is required to sign, certifying that you understand and will comply with all regulations, and carry this permit at all times while on the refuge.

2. You may enter the refuge no earlier than 4 a.m. and must exit the refuge by 2 hours after legal sunset.

3. You may possess only approved nontoxic shot while hunting on the refuge (see § 32.2(k)). This requirement applies only to the use of shotgun ammunition.

4. Waterfowl hunters may possess no more than 25 shotshells per person.

5. While hunting, all persons age 17 or younger must be in the presence and under direct supervision of a licensed or exempt hunter age 18 or older.

6. We allow take of beaver, feral hog, nutria, raccoon, and coyote incidental to any refuge hunt with weapons legal for that hunt until you take the daily bag limit of game.

7. You must check all game (name) taken prior to leaving the refuge at one of the self-clearing check stations indicated on the map in the refuge public use brochure.

8. We allow all-terrain vehicles (ATVs) and utility-type vehicle (UTVs) in accordance with State Wildlife Management Area regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches by 12 inches (66 cm by 30 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

9. We prohibit hunting within 150 feet (45 meters) of any public road, refuge road, trail or ATV trail, building, residence, or designated public facility.

10. We prohibit the possession or use of any type of trail-marking material.

11. We prohibit horses or mules.

12. We prohibit camping or overnight parking on the refuge.

13. We prohibit air-thrust boats on the refuge.

14. We prohibit all other hunting during refuge lottery deer hunts.

15. We allow waterfowl hunting on Wednesdays, Saturdays, and Sundays until 12 p.m. (noon) during the designated State duck season.

16. You must remove harvested waterfowl, temporary blinds, and decoys (see § 27.93 of this chapter) used for duck hunting by 1 p.m. daily.

17. We allow dogs to only locate, point, and retrieve when hunting for migratory game birds.

18. We prohibit accessing refuge property by boat from the Mississippi River.

19. We prohibit trapping.

20. We prohibit the possession of saws, saw blades, or machetes.

21. We prohibit the use or possession of alcohol while hunting (see § 32.2(j)).

22. We prohibit all commercial activities (including, but not limited to, guiding).

B. * * *

3. We allow the use of squirrel and rabbit dogs during designated small game with dog seasons. We allow up to two dogs per hunting party for squirrel hunting.

* * * * *

C. * * *

3. There is no application fee per person for each lottery hunt application (name/address/phone number).

4. You may place stands up to 2 days prior to established hunting season dates, and you must remove them no more than 2 days after the hunting season closes. You must mark your name and phone number on your stand. You are allowed one portable stand or blind on the refuge.

* * * * *

7. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken-hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken-hunter orange.

8. We prohibit nailing deer stands or steps to trees. We prohibit attaching any blind or stand to a tree by using any metal object inserted into the tree.

9. We prohibit the use of trail cameras.

* * * * *

D. * * *

8. We prohibit boat launching by trailer from all refuge roads and parking lots except at designated boat ramps.

* * * * *

D'Arbonne National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory game bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. You may enter the refuge no earlier than 4 a.m.

5. We prohibit hunting within 100 feet (30 meters (m)) of the maintained rights-of-way of roads. We prohibit hunting within 50 feet (15 m) or trespassing on above-ground oil, gas, or electrical transmission facilities.

6. We prohibit leaving boats, blinds, and decoys overnight.

7. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

8. Youths are generally defined as those individuals age 17 or younger, except that for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being

supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

9. We prohibit any person or group to act as a hunting guide, outfitter, or in any other capacity that any other individual(s) pays or promises to pay directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

10. We prohibit motorized boats in the No Gun Hunting Area (the "Beanfield") from November 1 through January 31.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, and A10 apply.

2. Specific open dates and open areas to small game hunting will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 2 hours after legal shooting hours.

5. You may possess only approved nontoxic shot for hunting (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

6. We allow hunting dogs only to locate, point, and retrieve when hunting for upland game species.

C. Big Game Hunting. We allow hunting of white-tailed deer on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, A10, and B4 apply.

2. Specific open dates and open areas will appear in the annual Public Use Regulations brochure.

3. You must check all deer taken during general Gun Deer Hunts at a refuge check station on the same day taken.

4. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

5. Deer hunters must wear hunter orange in accordance with State deer hunting regulations in Wildlife Management areas.

6. We prohibit hunters from placing or hunting from stands on pine trees with white-painted bands or rings.

7. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or any nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

8. We prohibit the hunting of big game species with dogs.

D. * * *

1. We prohibit leaving boats and other personal property on the refuge overnight.

* * * * *

3. We prohibit commercial fishing. For recreational fishing using commercial gear (slat traps, etc.) we require you to carry a Special Use Permit (FWS Form 3–1383), which is available at the refuge office.

* * * * *

Upper Ouachita National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of certain species of migratory birds on designated areas of the refuge as indicated in the annual Public Use Regulations brochure in accordance with State regulations and subject to the following conditions:

1. You must carry a signed refuge hunt permit (signed Public Use Regulations brochure) and must carry and fill out daily a Visitor Check-In Permit and Report (FWS Form 3–2405).

2. We allow migratory game bird hunting on designated areas as indicated in the annual Public Use Regulations brochure.

3. We allow waterfowl hunting until 12 p.m. (noon) during the State season.

4. You may enter the refuge no earlier than 4 a.m.

5. We prohibit hunting within 100 feet (30 meters (m)) of the maintained rights-of-way of roads and from or across all-terrain vehicle (ATV) trails. We prohibit hunting within 50 feet (15 m), or trespassing on aboveground oil, gas, or electrical transmission facilities.

6. We prohibit leaving boats, blinds, and decoys overnight.

7. We only allow hunting dogs to locate, point, and retrieve when hunting migratory game birds.

8. Youths are generally defined as those individuals age 17 or younger; for migratory bird hunts youth are defined as age 15 or younger. Youths younger than age 16 may hunt without hunter-education certification if they are accompanied by and under direct supervision of a person born before September 1, 1969, who has a valid hunting license or if they are accompanied by and under the direct supervision of a person who is age 18 or older and has proof of successful completion of a hunter-education course approved by Louisiana Department of Wildlife and Fisheries. Direct supervision means that the person being supervised is within a normal audible voice contact and in direct line of sight of the supervising person at all times while hunting. The supervising adult is responsible for ensuring that youth hunters do not violate refuge regulations.

9. We prohibit any person or group to act as a hunting guide or outfitter, or in any other capacity that receives payment directly or indirectly for services rendered to any other person or persons hunting on the refuge, regardless of whether the payment is for guiding, outfitting, lodging, or club membership.

10. We allow ATVs only on trails (see § 27.31 of this chapter) designated for their use and marked by signs. ATV trails are closed March 1 through August 31. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 lbs. (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 25 inches by 12 inches (62.5 cm by 30 cm) with a maximum of 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

B. Upland Game Hunting. We allow hunting of certain species of upland game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, and A10 apply.

2. Specific open dates and open areas to hunt small game will appear in the annual Public Use Regulations brochure.

3. We prohibit taking small game with firearms larger than .22 caliber rimfire, shotgun slugs, and buckshot.

4. You may enter the refuge no earlier than 4 a.m. and must exit no later than 2 hours after legal shooting hours.

5. You may possess only approved nontoxic shot for hunting (see § 32.2(k)). This requirement only applies to the use of shotgun ammunition.

C. Big Game Hunting. We allow hunting of certain species of big game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A5, A8, A9, A10, and B4 apply.

2. Specific open dates and open areas will appear in the Annual Public Use Regulations Brochure.

3. We prohibit leaving deer stands, blinds, cameras, and other equipment unattended.

4. Deer hunters must wear hunter orange in accordance with State deer hunting regulations in Wildlife Management Areas.

5. We prohibit hunters from placing stands or hunting from stands on pine trees with white-painted bands and/or rings.

6. We prohibit possession or distribution of bait or hunting with the aid of bait, including any grain, salt, minerals, or other feed or nonnaturally occurring attractant, on the refuge (see § 32.2(h)).

7. We prohibit the use of dogs for hog hunting.

D. * * *

2. We prohibit outboard motors in the Wigeon Ponds (only trolling motors allowed).

* * * * *

4. We prohibit leaving boats and other personal property on the refuge overnight (see § 27.93 of this chapter).

* * * * *

■ 17. Amend § 32.38 by:

■ a. Revising paragraph C.15 under the entry Moosehorn National Wildlife Refuge; and

■ b. Revising paragraphs B.3 and C.3 under the entry Umbagog National Wildlife Refuge.

The revisions read as follows:

§ 32.38 Maine.

* * * * *

Moosehorn National Wildlife Refuge

* * * * *

C. * * *

15. We prohibit hunting in the following areas:

i. The South Magurrewock Area: The boundary of this area begins at the intersection of the Charlotte Road and U.S. Route 1; it follows the Charlotte Road in a southerly direction to a point just south of the fishing pier and observation blind, where it turns in an easterly direction, crossing the East Branch of the Magurrewock Stream, and proceeds in a northerly direction along the upland edge of the Upper and Middle Magurrewock Marshes to U.S. Route 1 where it follows Route 1 in a southerly direction to the point of origin.

ii. The North Magurrewock Area: The boundary of this area begins where the northern exterior boundary of the refuge and Route 1 intersect; it follows the boundary line in a westerly direction to the railroad grade where it follows the main railroad grade and refuge boundary in a southwest direction to the upland edge of the Lower Barn Meadow Marsh; then it follows the upland edge of the marsh in a southerly direction to U.S. Route 1 where it follows Route 1 to the point of origin.

iii. The posted safety zone around the refuge headquarters: The boundary of this area starts where the snowmobile trail intersects with Charlotte Road. The boundary follows the southern edge of the field, across the abandoned Maine Central Railroad grade, where it follows the snowmobile trail in a northwesterly direction to Barn Meadow Road. It proceeds across Barn Meadow Road to the South Fireline, where it follows the South Fireline to the Headquarters Road. It follows the Headquarters Road in a southerly direction to Two Mile Meadow Road. It follows the westerly side of Two Mile Meadow Road to the intersection with Mile Bridge Road. It then follows Mile Bridge Road to the intersection with Hanson Pit Road, then along Hanson Pit Road leaving the road in an easterly direction at the site of the old crossing, across the abandoned Maine Central Railroad grade to Charlotte Road (directly across from the Moosehorn Ridge Road gate). The line follows Charlotte Road in a northerly direction to the point of origin.

iv. The Southern Gravel Pit: The boundary of this area starts at a point where Cranberry Brook crosses the Charlotte Road and proceeds south along the Charlotte Road to the Baring/Charlotte Town Line, east along the Town Line to a point where it intersects the railroad grade where it turns in a northerly direction, and follows the railroad grade to Cranberry Brook, following Cranberry Brook in a westerly direction to the point of origin.

* * * * *

Umbagog National Wildlife Refuge

* * * * *

B. * * *

3. We open the refuge to hunting during the hours stipulated under State hunting regulations. You must unload all hunting firearms (see § 27.42 of this chapter) and nock no arrows outside of legal hunting hours.

* * * * *

C. * * *

3. We allow prehunt scouting of the refuge; however, we prohibit dogs and hunting firearms (see § 27.42 of this chapter) during prehunt scouting.

* * * * *

■ 18. Amend § 32.39 by:

■ a. Revising paragraphs A.1, A.3, and C.13 under the entry Blackwater National Wildlife Refuge;

■ b. Revising paragraph C.12 under the entry Eastern Neck National Wildlife Refuge; and

■ c. Under the entry Patuxent Research Refuge:

■ i. Revising paragraphs A.12, B.2, C.6, C.7, and C.8;

■ ii. Removing paragraph C.16;

■ iii. Redesignating paragraphs C.17 through C.20 as C.16 through C.19, respectively;

■ iv. Revising newly redesignated paragraphs C.17, C.18, and C.19; and

■ v. Revising paragraphs D.15.iv and D.15.v.

The revisions read as follows:

§ 32.39 Maryland.

* * * * *

Blackwater National Wildlife Refuge

A. * * *

1. We require you to obtain a refuge waterfowl hunting permit using the Waterfowl Lottery Application (FWS Form 3–2355) or a signed refuge permit (signed brochure) while hunting on refuge property.

* * * * *

3. We allow only hunters possessing a valid refuge waterfowl hunting permit issued by the refuge to participate in the waterfowl hunt during designated days.

* * * * *

C. * * *

13. Disabled persons may have an assistant during the hunt in designated areas of the refuge. Persons assisting disabled hunters must be at least age 18 and obey all refuge, State, and Federal laws and regulations. Non-hunting assistants assisting disabled hunters must not be afield with a hunting firearm, bow, or other hunting device. Assistants who wish to hunt must abide by the conditions in C1 and C3. Assistants may not enter a designated disabled hunting area unless they are accompanied by a certified disabled hunter. All refuge-provided hunt blinds are reserved for disabled hunters only; however, when a certified disabled hunter and their assistant occupy the same blind, both may take game.

* * * * *

Eastern Neck National Wildlife Refuge

* * * * *

C. * * *

12. Disabled persons may have an assistant during the hunt on designated areas of the refuge. Persons assisting disabled hunters must be at least age 18 and obey all refuge, State, and Federal laws and regulations. Non-hunting assistants assisting disabled hunters must not be afield with a hunting firearm, bow, or other hunting device.

Assistants who wish to hunt must abide by the conditions in C1 and C3. Assistants participating in a disabled hunt must be accompanied by a certified disabled hunter.

* * * * *

Patuxent Research Refuge

A. * * *

12. Goose, duck, and dove hunting is suspended during the muzzleloader and firearms seasons, with the exceptions that waterfowl hunting will remain open during the 2-day January firearms season, during the early muzzleloader season, and waterfowl hunters are restricted to hunting only Blue Heron Pond, Lake Allen, and Area Z.

* * * * *

B. * * *

2. You may possess only approved nontoxic shot while hunting in the field (see § 32.2(k)), except for the use of .22-caliber rimfire rifles during the months of December and January only to hunt squirrel.

* * * * *

C. * * *

6. We require turkey hunters to pattern their hunting weapons prior to going afield. Contact refuge headquarters for more information.

7. Prior to issuing a hunt permit, we require you to pass a yearly proficiency test with each hunting weapon used. See A1 for issuing information.

8. We only allow the use of a hunting shotgun, muzzleloader, or bow and arrow according to refuge hunting regulations.

* * * * *

17. North Tract: We allow shotgun, muzzleloader, and bow hunting in accordance with the following: Conditions C1 through C16 apply.

18. Central Tract: Headquarters/Mills Race (MR) Lottery Hunt: We only allow shotgun and bow hunting in accordance with the following: Conditions C1 through C15 apply (except C8).

19. South Tract: We allow shotgun, muzzleloader, and bow hunting in accordance with the following: Conditions C1 through C16 apply.

D. * * *

15. * * *

iv. Anglers may fish from April 1 until mid-October, as posted. We also reserve the right to close Cash Lake at any time.

v. We allow fishing from legal sunrise to legal sunset.

* * * * *

■ 19. Amend § 32.40 by:

■ a. Revising paragraphs A.4, A.5, A.9, C.9, and D.1 under the entry Assabet River National Wildlife Refuge;

■ b. Revising paragraphs A.5, A.10, and C.8 under the entry Great Meadows National Wildlife Refuge;

■ c. Revising paragraphs D.1 and D.3 under the entry Nantucket National Wildlife Refuge; and

■ d. Revising the heading of paragraph A, and paragraphs A.6, A.11, C.7, and C.9 under the entry Oxbow National Wildlife Refuge.

The revisions read as follows:

§ 32.40 Massachusetts.

* * * * *

Assabet River National Wildlife Refuge

A. * * *

4. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

5. During any season when it is legal to hunt deer with a shotgun or muzzleloader, we require all hunters, including archers and small game hunters, to wear a minimum of 500 square inches (3,226 square centimeters) of solid-orange clothing or material in a conspicuous manner on their chest, back, and head. During all other times, if you are engaged in woodcock hunting on the refuge, you must wear a minimum of a solid-orange hat.

* * * * *

9. You may begin scouting hunting areas 1 month prior to the opening day of your permitted season. We require possession of refuge permits (Migratory Bird Hunt Application, FWS Form 3–2357) while scouting.

* * * * *

C. * * *

9. We prohibit construction or use of permanent structures while hunting.

* * * * *

D. * * *

1. We allow fishing from designated locations on the banks of Puffer Pond. We prohibit the use of motorized and non-motorized boats on Puffer Pond.

* * * * *

Great Meadows National Wildlife Refuge

A. * * *

5. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

* * * * *

10. You may begin scouting hunting areas beginning 1 month prior to the opening day of your permitted season. We require possession of refuge permits (FWS Form 3–2357) while scouting. We prohibit the use of dogs during scouting.

* * * * *

C. * * *

8. We prohibit construction or use of permanent structures while hunting.

* * * * *

Nantucket National Wildlife Refuge

* * * * *

D. * * *

1. We reserve the right to close the refuge shoreline and beach area to surf fishing and over-sand vehicle use during the period of April 1 through mid-September annually, based on biological needs and beach conditions. Seasonal closures are delineated with posted signs. A portion of the northernmost area of the shoreline, commonly referred to as the point, is posted closed from April 1 through mid-September.

* * * * *

3. We require a permit obtained from the Trustees of Reservations for the use of over-sand, surf-fishing vehicles on the refuge.

* * * * *

Oxbow National Wildlife Refuge

A. Migratory Game Bird Hunting. * * *

6. We prohibit use of motorized vehicles on the refuge. The refuge will provide designated parking areas for hunters. You must display issued hunter parking permits (generated from the Migratory Bird Hunt Application, FWS Form 3–2357) on their dashboards when parked in designated hunter parking areas.

* * * * *

11. You may begin scouting hunting areas 1 month prior to the opening day of your permitted season. We require possession of refuge permits while scouting. We prohibit the use of dogs during scouting.

* * * * *

C. * * *

7. You may use decoys to hunt turkey.

* * * * *

9. We prohibit construction or use of permanent structures while hunting.

* * * * *

■ 20. Amend § 32.41, the entry for Detroit River International Wildlife Refuge, by revising paragraphs A.4, B.1, B.2, and C to read as follows:

§ 32.41 Michigan.

* * * * *

Detroit River International Wildlife Refuge

A. * * *

4. For hunting, you may possess only approved nontoxic shot while in the field, including shot shells used for hunting wild turkey (see § 32.2(k)). Discarded shells are considered litter.

* * * * *

B. * * *

1. Conditions A1, A2, A3, A5, A6, A7, A8, and A9 apply.

2. You may possess only approved nontoxic shot (see § 32.2(k)) while in the field with the following exception: While hunting fox, coyotes, and raccoons in units where we allow it, you may use single projectile shot such as bullets, slugs, or muzzleloader bullets containing lead. We prohibit the use of buckshot for any hunting on the refuge. Discarded shells are considered litter.

C. Big Game Hunting. We allow hunting of deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A3, A4, A5, A6, A8, and A9 apply.

2. We prohibit the distribution of bait or hunting with the aid of bait, salt, minerals, or other ingestible attractant (see § 32.2(h)).

3. For deer hunting, you may use only single projectile shot. We prohibit the use of buckshot for any hunting on the refuge. Discarded shells are considered litter.

4. We allow portable tree stands for deer hunting.

5. We allow only one tree stand per hunter per refuge unit.

6. We do not require hunters to remove tree stands at the end of each day's hunt, but we strictly enforce State rules on tree stands.

7. For Humbug Marsh Only:

i. You must obtain permits for this unit by entering the Michigan Department of Natural Resources annual drawing.

ii. You must possess a valid permit for the date you are hunting in the Humbug Marsh Unit.

iii. We will provide fixed hunting platforms and blinds for selected hunters.

8. The Fix Unit is closed to firearm deer hunting. We allow only archery deer hunting in the Fix Unit.

* * * * *

■ 21. Amend § 32.43 by:

■ a. Revising paragraphs A, D.1, D.2, and D.8 under the entry Coldwater River National Wildlife Refuge;

■ b. Revising paragraphs A, B, C, D.1, D.2, and D.7 under the entry Dahomey National Wildlife Refuge;

■ c. Revising paragraphs A.2, A.3, A.13, and A.14 under the entry Hillside National Wildlife Refuge;

■ d. Revising paragraphs A.2, A.3, and A.9 under the entry Holt Collier National Wildlife Refuge;

■ e. Revising paragraphs A.2, A.3, and A.12 under the entry Mathews Brake National Wildlife Refuge;

■ f. Revising paragraphs A.2, A.3, A.13, and A.14 under the entry Morgan Brake National Wildlife Refuge;

■ g. Revising paragraphs A.2, A.3, and A.13 under the entry Panther Swamp National Wildlife Refuge;

■ h. Revising the entry for Sam D. Hamilton Noxubee National Wildlife Refuge;

■ i. Under the entry St. Catherine Creek National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.9, A.11, A.12, and A.14;

■ ii. Revising paragraphs B.3.iii and B.6;

■ iii. Revising paragraphs C.3, C.4, C.7, and C.9;

■ iv. Adding paragraph C.13; and

■ v. Revising paragraph D introductory text and paragraphs D.1 and D.5;

■ j. Revising the entry for Tallahatchie National Wildlife Refuge; and

■ k. Revising paragraphs A.2, A.3, A.10, and A.13 under the entry Yazoo National Wildlife Refuge.

The addition and revisions read as follows:

§ 32.43 Mississippi.

* * * * *

Coldwater River National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must possess and carry a valid, signed refuge hunting permit (Visitor Check-In Permit and Report, FWS Form 3–2405). While hunting on the refuge, all persons younger than age 16 ("youth hunter") must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 ("licensed hunter"). A hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359), available at each refuge information station, and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the reverse side of the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report "0." We prohibit hunters possessing more than one Big Game Harvest Report at a time.

5. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with "No Hunting" or "Area Closed" signs.

6. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

7. During the refuge deer firearm season (to include primitive weapons and youth gun hunt) all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge's general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

8. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

9. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94 of this chapter) from the hunting area following each morning's hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit all-terrain vehicles (ATVs, see § 27.31(f) of this chapter), horses, and mules on the refuge. We prohibit the overnight storage of boats on the refuge.

11. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

12. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

13. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

14. You are allowed no more than 25 shotshells per person in the field.

* * * * *

D. * * *

1. Condition A12 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

* * * * *

8. We allow take of frog only with a Special Use Permit (FWS Form 3–1383–G).

Dahomey National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must carry a valid, signed refuge hunting permit (Visitor Check-In Permit and Report, FWS Form 3–2405). While hunting on the refuge, all persons younger than age 16 (“youth hunter”) must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 (“licensed hunter”). A hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359), available at each refuge information station, and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report “0.” We prohibit hunters possessing more than one Big Game Harvest Report at a time.

5. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with “No Hunting” or “Area Closed” signs.

6. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

7. During the refuge deer firearm season (to include primitive weapons and youth gun hunt) all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge’s general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

8. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

9. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94 of this chapter) from the hunting area following each morning’s hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) (see § 27.31(f) of this chapter), horses, and mules on the refuge.

11. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

12. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

13. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

14. You are allowed no more than 25 shotshells per person in the field.

B. Upland Game Hunting. We allow hunting of quail, squirrel, rabbit, and raccoon (raccoon by general Special Use Permit [FWS Form 3–1383–G] only) on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A7, and A10 through A13 apply.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting small game with a shotgun. Small game also may be hunted with .22 magnums, .17 calibers, and .22 caliber rimfire rifles and archery equipment using arrows with points other than broadheads.

3. You may use dogs, but dogs must remain under the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

4. We prohibit the cutting or removal of trees and other vegetation (see § 27.51 of this chapter).

5. We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A7, and A10 through A13 apply.

2. We prohibit dogs for any big game hunt.

3. We prohibit possession of any drug on any arrow for bow hunting (see § 32.2(g)).

4. We prohibit organized drives for deer.

5. We prohibit hunting or shooting across any open, fallow, or planted field from ground level.

6. We prohibit the construction of, and hunting from, any permanent stands or blinds on the refuge. We allow valid permit holders to possess and hunt from one portable stand or blind on the refuge. You must permanently and legibly write your name and phone number on all stands on the refuge. Stands left in the area do not reserve the hunting locations. You may place stands up to 2 days prior to the hunt, and you must remove them no more than 2 days after the refuge’s deer season closes. We may confiscate and dispose of stands not in compliance with these regulations. Ground blinds must display a minimum 400 square inches (2,581 square centimeters) of fluorescent orange that is visible from all sides. We prohibit nailing deer stands and/or steps to trees and attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

7. Hunters using a climbing tree stand must use a fall-arrest system manufactured to Treestand Manufacturers Association standards.

8. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter).

9. We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

10. We prohibit the use of buckshot on the refuge.

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A11 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

* * * * *

7. We allow take of frog only by Special Use Permit (FWS Form 3–1383–G).

* * * * *

Hillside National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

14. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) only on designated trails (see § 27.31 of this chapter; see refuge brochure map) from September 15 through February 28. We prohibit horses and mules.

* * * * *

Holt Collier National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

9. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Mathews Brake National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

12. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Morgan Brake National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

14. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) only on designated trails (see § 27.31 of this chapter; see refuge brochure map) from September 15 through February 28. We prohibit horses and mules.

* * * * *

Panther Swamp National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

Sam D. Hamilton Noxubee National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, woodcock, and coot on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must purchase a refuge waterfowl permit (Waterfowl Lottery Application; FWS Form 3–2355) for waterfowl hunting in addition to meeting other applicable State and Federal requirements. No more than two companions may accompany each permitted hunter, and we do not require these companions to purchase permits. Permits are nontransferable and only issued to hunters ages 16 and older. Permit holders can hunt as standby hunters for any date for which waterfowl hunting is open. Youth age 15 or younger are not required to obtain a refuge waterfowl permit and can obtain a free permit from the refuge's office.

2. Information on hunts and hunt dates are available at refuge headquarters, on the refuge Web site, and as specified in the refuge brochure.

3. You must remove all decoys, blind material, and harvested game and return to the check station by 1 p.m. each day (see §§ 27.93 and 27.94 of this chapter).

4. All youth hunters age 15 and younger must remain within sight and normal voice contact of an adult age 21 or older. One adult may supervise not more than two youth hunters.

5. All waterfowl hunters must check-in and check-out at the refuge's duck

check station both before and after a day's hunt.

6. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

7. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

8. You may possess only approved nontoxic shot while hunting within wetlands and green-tree reservoirs (see § 32.2(k)). Waterfowl hunters are limited to 25 shotshells per person.

9. We prohibit leaving any personal property, including, but not limited to, boats or vehicles of any type, geocaches, and cameras, overnight on the refuge (see § 27.93 of this chapter). You may not bring any mechanized equipment into the Noxubee Wilderness Area, and you must remove all personal property daily from the Noxubee Wilderness Area. Outside the Noxubee Wilderness Area, you may leave properly labeled tree stands used for deer hunting and trotlines and jugs used for fishing overnight.

10. During the deer firearm (primitive or modern gun) hunts, any person hunting species other than waterfowl, accompanying another person hunting species other than waterfowl, or walking off-trail within areas open to deer hunting must wear at least 500 square inches (3,226 square centimeters (cm)) of unbroken fluorescent-orange material visible above the waistline as an outer garment at all times. Ground blinds when occupied must display a minimum of 400 square inches (2,581 square cm) of unbroken fluorescent-orange material.

11. We allow unleashed dogs for retrieval of migratory and upland game only. Livestock is prohibited, and pets must remained restrained and under the owner's control.

12. We prohibit marking trees and using flagging tape, reflective tacks, and other similar marking devices.

13. We require all hunters and anglers to record hours active and game harvested using the Visitor Check-In Permit and Report (FWS Form 3–2405).

14. We require all users to possess and display a valid Entrance Pass. You may use a current Federal Recreational Lands Pass or valid Federal Migratory Bird Hunting and Conservation Stamp (Federal Duck Stamp) as the Entrance Pass.

15. Waterfowl hunters must stay within 100 feet (30.5 meters (m)) of the assigned hunt location. You may exceed 100 feet (30.5 m) when retrieving downed birds.

16. We prohibit using real or artificial agricultural grain baits, salts and other minerals, scents, and other food-like attractants (see § 32.2(h)). We allow you to use baited lines for fishing on the refuge.

17. We prohibit off-road vehicle use including the use of all-terrain vehicles (ATVs), utility-type vehicles (UTVs), and livestock, including horses and mules.

B. Upland Game Hunting. We allow hunting of squirrel, rabbit, quail, opossum, and raccoon on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. When waterfowl hunting is actively taking place, we prohibit all public use other than waterfowl hunting within the designated areas for waterfowl hunting.

2. We allow hunting of squirrel, raccoon, rabbit, quail, and opossum with unleashed dogs during designated hunts. All pets must remain restrained and within the immediate control of the owner.

3. We allow raccoon and opossum hunting between the hours of legal sunset and legal sunrise.

4. Conditions A2, A4, A6 through A14, A16, and A17 apply.

5. We prohibit hunting or entry into areas designated as being "closed" (see refuge brochure map).

6. You may take incidental species (coyote, beaver, nutria, and feral hog) during any hunt with those weapons legal during those hunts.

7. Bobwhite quail and rabbit hunters are required to wear at least a solid hunter orange vest or cap.

C. Big Game Hunting. We allow hunting of white-tailed deer and turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A2, A4, A6 through A14, A16, A17, B1, B2, B5 and B6 apply.

2. You must purchase a refuge quota deer permit (Quota Deer Hunt Application; FWS Form 3–2354) in addition to meeting State requirements for all refuge deer hunts. Permits are nontransferable. Youth age 15 or younger are not required to a purchase a refuge quota deer permit and can obtain a free permit from the refuge's office.

3. We prohibit organized drives for deer.

4. You may place one portable tree stand or ground blind for deer hunting on the refuge only during the open deer season. You must clearly label the stand or blind with the name, address, and phone number of the hunter. When not in use and left on the refuge, you must place stands in a non-hunting position at ground level.

5. While climbing a tree, installing a tree stand that uses climbing aids, or hunting from a tree stand on the refuge, you must use a fall-arrest system (full body harness) that is manufactured to the Treestand Manufacturer's Association's standards.

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. The general sport fishing, boating, and bow fishing season extends from March 1 through October 31, except for the shoreline of Bluff Lake from the Bluff Lake Boardwalk to the visitor center, the entire Noxubee River, and all borrow pit areas along Highway 25 that are open year-round to fishing.

2. Conditions A2, A6, A7, A9 through A14, A16, A17, B1, and B5 apply.

3. Anglers must keep boat travel at idle speed, and they must not create a wake when moving.

4. We prohibit limb lines, jug fishing, trotlines, snag lines, and hand grappling in Ross Branch, Bluff, and Loakfoma Lakes as well as areas within 100 yards of refuge water and transportation structures.

5. When left unattended, anglers must tag fishing gear with their name, address, and phone number. Anglers must check all gear within 24 hours each day or remove these devices.

6. Trotlining:

i. Anglers must label each end of the trotline floats with the owner's name, address, and phone number.

ii. We limit trotlines to one line per person, and we allow no more than two trotlines per boat.

iii. Anglers must tend all trotlines every 24 hours and remove them when not in use.

iv. Trotlines must possess at least 6-inch (15.2-centimeter) cotton string leads.

7. Jug fishing:

i. Anglers must label each jug with their name, address, and phone number.

ii. Anglers must check all jugs every 24 hours and remove them when not in use.

8. We prohibit nighttime bow fishing.

9. We prohibit fishing tournaments on all refuge waters.

10. We prohibit the taking of frogs, turtles, and crawfish (see § 27.21 of this chapter).

11. We prohibit the use of airboats, sailboats, hovercrafts, and inboard-water-thrust boats such as, but not limited to, personal watercraft, watercycles, and waterbikes.

12. We prohibit using nets of any type to capture free-roaming fish or wildlife. Fishing nets can be used to recover fish caught by hook and line.

St. Catherine Creek National Wildlife Refuge

A. * * *

1. We allow hunting in Butler Lake, Salt Lake, and Gillard Lake from ½ hour before legal sunrise until 12 p.m. (noon) on Wednesdays, Saturdays, and Sundays.

* * * * *

9. Waterfowl hunters are allowed no more than 25 shotshells per person.

* * * * *

11. We allow all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) in accordance with State WMA regulations and size specifications on designated trails (see § 27.31 of this chapter) from scouting season until February 28. An ATV is an off-road vehicle with factory specifications not to exceed the following: Weight 750 pounds (337.5 kilograms), length 85 inches (212.5 centimeters (cm)), and width 48 inches (120 cm). We restrict ATV tires to those no larger than 26 inches (66 cm) by 12 inches (30 cm) with a maximum 1-inch (2.5-cm) lug height and a maximum allowable tire pressure of 7 psi (48 kPa) as indicated on the tire by the manufacturer.

12. You must be age 16 or older to operate an ATV or UTV on the refuge.

* * * * *

14. We prohibit the following acts: Use or possession of alcohol while hunting (see § 32.2(j)); entering the refuge from private property; hunters entering the refuge from public waterways; overnight parking; parking or hunting within 150 feet (45 meters) of any petroleum facility or equipment, or refuge residences and buildings; parking by hunters in refuge headquarters parking lot; and use of handguns for hunting on the refuge.

B. * * *

3. * * *

iii. We prohibit the use of boats, ATVs, and UTVs.

* * * * *

6. We prohibit the following acts: Target practice; and the possession of any trail-marking material.

C. * * *

3. You must wear a minimum of 500 square inches (3,226 square centimeters) of unbroken hunter orange as the outermost layer of clothing on the chest and back, and a hat or cap of unbroken hunter orange. You must wear the solid-hunter-orange items while in the field.

4. While hunting, all persons under age 16 must be in the presence and under direct supervision of a licensed or exempt hunter at least age 21.

* * * * *

7. We prohibit nailing deer stands and/or steps to trees. We prohibit attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

* * * * *

9. You may place stands up to 2 days prior to established hunting season dates, and you must remove them no more than 2 days after the hunting season closes. You must mark your stand with your name and phone number. We allow each hunter one portable stand or blind on the refuge.

* * * * *

13. We prohibit the use of trail cameras.

D. * * *. We allow fishing during daylight hours only from February 1–November 15 in accordance with State regulations and subject to the following conditions:

1. We prohibit the use of ATVs and UTVs (see § 27.31(f) of this chapter).

* * * * *

5. We prohibit taking alligator gar.

* * * * *

Tallahatchie National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of migratory waterfowl, coots, snipe, and woodcock on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. All hunters must comply with all State hunter education requirements. All hunters age 16 and older must possess and carry a signed North Mississippi NWR hunting permit (code 606, available from the Mississippi Department of Wildlife, Fisheries, and Parks). While hunting on the refuge, all persons younger than age 16 ("youth hunter") must be in the presence and under the direct supervision of a licensed or exempt hunter at least age 21 ("licensed hunter"). A licensed hunter supervising a youth hunter must hold all required licenses and permits.

2. General refuge hours are legal sunrise to legal sunset. During hunting season, hunters may enter the refuge at 4 a.m. and must exit the refuge no later than 2 hours after legal sunset except during raccoon and frog hunts.

3. We allow hunting of migratory game birds, including under the Light Goose Conservation Order, only on Wednesdays, Saturdays, and Sundays ending at 12 p.m. (noon).

4. We prohibit public hunting north of Mississippi Highway 8.

5. Each hunter must obtain a daily Big Game Harvest Report (FWS Form 3–2359) available at each refuge information station and follow the printed instructions on the card. You must display the card in plain view on the dashboard of your vehicle so that the personal information is readable. Prior to leaving the refuge, you must complete the card and deposit it at one of the refuge information stations. Include all game harvested, and if you harvest no game, report "0." We prohibit hunters possessing more than one Big Game Harvest Report at a time.

6. We may close certain areas of the refuge for sanctuary or administrative purposes. We will mark those areas with "No Hunting" or "Area Closed" signs.

7. We restrict motor vehicle use to roads designated as vehicle access roads on the refuge map (see § 27.31 of this chapter). We prohibit blocking access to any road or trail entering the refuge (see § 27.31(h) of this chapter). It is unlawful to hunt from or shoot into the 100-foot (30.5-meter) zone along either side of designated roads and parking lots.

8. During the refuge deer firearm season (to include primitive weapons and youth gun hunt), all hunters and visitors on the refuge except waterfowl hunters and nighttime raccoon hunters must wear in full view a minimum of 500 square inches (3,226 square centimeters (cm)) of solid, unbroken, fluorescent orange. Deer archery hunters on the refuge must also wear in full view a minimum of 500 square inches (3,226 square cm) of solid, unbroken, fluorescent orange when there is a State gun season on private land. When hunting quail or rabbit on a refuge outside the refuge's general gun and primitive weapon season, hunters must wear a fluorescent orange vest or cap.

9. We only allow dogs on the refuge when specifically authorized for hunting. We encourage the use of dogs to retrieve dead or wounded waterfowl. Dogs must remain in the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

10. You must remove decoys, blinds, boats, other personal property, and litter (see §§ 27.93 and 27.94) from the hunting area following each morning's hunt. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

11. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) (see § 27.31(f) of this chapter), horses, and mules on the refuge.

12. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

13. We prohibit all commercial activities, including guiding or participating in a paid guided hunt.

14. We prohibit possession of bait in the field, placement of bait, and hunting over bait (see § 32.2(h)).

15. You are allowed no more than 25 shotshells per person in the field.

B. Upland Game Hunting. We allow hunting of quail, squirrel, rabbit, and raccoon (raccoon by general Special Use Permit [FWS Form 3–1383–G] only) on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A8, and A10 through A14 apply.

2. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting for small game with a shotgun. Small game also may be hunted with .22 magnums, .17 calibers, and .22 caliber rimfire rifles and archery equipment using arrows with points other than broadheads.

3. You may use dogs, but they must remain under the immediate control of their handlers at all times (see § 26.21(b) of this chapter).

C. Big Game Hunting. We allow hunting of white-tailed deer and feral hog on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, A4 through A8, and A10 through A13 apply.

2. We prohibit dogs for any big game hunt.

3. We prohibit possession of any drug on any arrow for bow hunting (see § 32.2(g)).

4. We prohibit organized drives for deer.

5. We prohibit hunting or shooting across any open, fallow, or planted field from ground level.

6. We prohibit the construction of, and hunting from, any permanent stands or blinds on the refuge. We allow valid permit holders to possess and hunt from one portable stand or blind on the refuge. You must permanently and legibly write your name and phone number on all stands on the refuge. Stands left on the area do not reserve the hunting locations. You may place stands up to 2 days prior to the hunt, and you must remove them no more than 2 days after the refuge's deer season closes. We may confiscate and dispose of stands not in compliance with these regulations. Ground blinds must display a minimum 400 square inches (2,581 square centimeters) of fluorescent orange that is visible from all sides. We prohibit nailing deer stands and/or steps to trees and attaching any blind or stand to a tree by any metal object inserted into the tree (see § 32.2(i)).

7. Hunters using a climbing tree stand must use a fall-arrest system manufactured to Treestand Manufacturers Association standards.

8. We prohibit cutting or removing trees and other vegetation (see § 27.51 of this chapter). We prohibit the use of flagging, paint, blazes, tacks, or other types of markers.

9. We prohibit the use of buckshot on the refuge.

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Condition A12 applies.

2. All anglers must carry a valid refuge permit (Visitor Check-In Permit and Report, FWS Form 3–2405), certifying that they understand and will comply with all regulations.

3. We only allow bank or boat sport fishing south of Mississippi Highway 8.

4. We prohibit possession or use of jugs, seines, nets, hand-grab baskets, slat traps/baskets, or any other similar devices and commercial fishing of any kind.

5. We only allow trotlines, yo-yos, limb lines, crawfish traps, or any other similar devices for recreational use. You must tag or mark them with the angler's full name and full residence address, including zip code written with waterproof ink, legibly inscribed or legibly stamped on the tag, and you must attend the devices a minimum of once daily. When not attended, you must remove these devices (see § 27.93 of this chapter) from the refuge.

6. We prohibit snagging or attempting to snag fish.

7. We allow crawfishing.

8. We allow take of frog only with a Special Use Permit (FWS Form 3–1383–G).

Yazoo National Wildlife Refuge

A. * * *

2. All youth hunters age 15 and younger must be in the presence and direct supervision of a Mississippi licensed or exempt hunter, age 21 or older. One adult may supervise no more than one youth hunter.

3. Before hunting or fishing, all participants must display their Daily Visitor Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. All cards must be returned upon completion of the activity and before leaving the refuge.

* * * * *

10. For hunting, you may possess only approved nontoxic shot (see § 32.2(k)).

* * * * *

13. Valid permit holders may incidentally take opossum, coyote, beaver, bobcat, nutria, and feral hog in any refuge hunt season with weapons legal for that hunt.

* * * * *

■ 22. Amend § 32.44 by:

■ a. Revising the entry for Great River National Wildlife Refuge; and

■ b. Revising the entry for Middle Mississippi River National Wildlife Refuge.

The revisions read as follows:

§ 32.44 Missouri.

* * * * *

Great River National Wildlife Refuge

Refer to § 32.32 (Illinois) for regulations.

Middle Mississippi River National Wildlife Refuge

Refer to § 32.32 (Illinois) for regulations.

* * * * *

■ 23. Amend § 32.46 by revising paragraphs C.1, C.2, C.4, and C.9 under the entry Fort Niobrara National Wildlife Refuge to read as follows:

§ 32.46 Nebraska.

* * * * *

Fort Niobrara National Wildlife Refuge

* * * * *

C. * * *

1. We require the submission of a Big/Upland Game Hunt Application (FWS Form 3–2356). You must possess and carry a signed refuge hunt permit (signed brochure) when hunting. We require hunters to complete a Big Game Harvest Report (FWS Form 3–2359) and return it to the refuge at the conclusion of the hunting season.

2. We allow hunting with muzzleloader and archery equipment. We prohibit hunting with firearms capable of firing cartridge ammunition.

* * * * *

4. We allow hunting in the area defined as those refuge lands situated north and west of the Niobrara River. We allow access to this area only from designated refuge parking areas and the Niobrara River.

* * * * *

9. We prohibit permanent tree stands, nails, screw-in steps, or other items that penetrate the outer bark of a tree (see § 32.2(i)). We prohibit leaving tree stands and ground blinds in the same location for more than 7 consecutive days. You must label unattended tree

stands, elevated platforms, and ground blinds with your name and address; the label must be legible from the ground. You may put up tree stands, elevated platforms, and ground blinds, but no earlier than opening day of deer season; you must remove them by the last day of deer season.

* * * * *

■ 24. Amend § 32.48, the entry for Umbagog National Wildlife Refuge, by revising paragraphs A.1 and C.3 to read as follows:

§ 32.48 New Hampshire.

* * * * *

Umbagog National Wildlife Refuge

A. * * *

1. You must wear hunter-orange clothing or material in accordance with State of Maine regulations for the season and/or species you are hunting; one article of hunter-orange clothing is required during moose season, and two articles are required during firearm and muzzleloader season for deer.

* * * * *

C. * * *

3. We allow prehunt scouting of the refuge; however, we prohibit dogs and hunting firearms during prehunt scouting.

* * * * *

■ 25. Amend § 32.5, the entry for Montezuma National Wildlife Refuge, by revising paragraphs A, B, and C.11 to read as follows:

§ 32.51 New York.

* * * * *

Montezuma National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow waterfowl, Canada goose, and snow goose hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. For the regular waterfowl season:

i. We require daily refuge permits (Migratory Bird Hunt Report, FWS Form 3–2361) and reservations. You must possess and carry refuge permits while in the field and present them upon request to any law-enforcement officer.

ii. We allow hunting only on Tuesdays, Thursdays, and Saturdays during the established refuge season set within the State western zone season. We allow a youth waterfowl hunt during the Saturday of the State's established youth waterfowl hunt dates each year.

iii. Except for opening day, we take telephone reservations from 8:30 a.m. to 9 a.m. on Tuesdays, Thursdays, and Saturdays for the next hunt day.

iv. We take opening day reservations between 8:30 a.m. and 9 a.m. on the Thursday of the week before the season opener (Note: This is not the Thursday directly before the opener). We take youth hunt reservations between 8:30 a.m. and 9 a.m. on the Thursday of the week before the youth hunt (Note: This is not the Thursday directly before the youth hunt.).

v. The reservation telephone number is 315–568–4136.

vi. All telephone reservations are on a first-come, first-served basis.

vii. If you have a reservation for Tschache Pool, you may bring one companion; we will determine party limits for other areas annually.

viii. You may request the parking area of your choice when making reservations; parking areas are given on a first-come, first-served basis.

ix. Only refuge personnel may move parking signs and blinds.

x. All hunters with reservations and their hunting companions must check-in at the Route 89 Hunter Check Station area at least 1 hour before legal shooting time or forfeit their reservation.

xi. You must set up in your chosen hunting spot before legal shooting time.

xii. Forfeited reservations become available on a first-come, first-served basis to standby hunters at the Route 89 Hunter Check Station.

xiii. In Tschache Pool, you must use motorless boats to hunt, and we limit hunters to one boat per reservation. We also limit hunters to one motor vehicle in the Tschache Pool area per reservation.

xiv. We prohibit shooting from any dike or within 50 feet (15.2 meters) of any dike or road, or from within 500 feet (152.4 meters) of the Tschache Pool observation tower. We do not limit hunting to specific blind sites.

xv. We will announce selection procedures for hunting sites on areas other than Tschache Pool annually.

xvi. You may possess a maximum of 15 nontoxic shot shells for hunting while in the field (see § 32.2(k)); you may not take more than 15 shot shells per hunter into the hunting area.

xvii. You must stop hunting at 12 p.m. (noon), and you must check-out and be out of the hunting area by 1 p.m.

xviii. We require proof of successful completion of the New York State Waterfowl Identification Course, the Montezuma Nonresident Waterfowl Identification Course, or a suitable nonresident State Waterfowl Identification Course to hunt in the refuge; all hunters must show proof each time they hunt, in addition to showing their valid hunting license and signed Federal Migratory Bird Hunting and Conservation Stamp (Federal Duck Stamp).

xix. You must possess, carry, and present upon request to any law enforcement officer a valid daily hunt permit card (Migratory Bird Hunt Report, FWS Form 3–2361). We also require you to return the daily hunt permit card at the end of hunting. You can obtain a permit at the Hunter Check Station during the check-in process, and you can return it to the Hunter Check Station or at the box located at the north end of the Tschache Pool dike.

2. For Canada goose and snow goose hunting:

i. We allow hunting of Canada goose during the New York State September (or "early") season and of snow goose during portions of the New York State snow goose season and portions of the period covered by the Light Goose Conservation Order according to New York State regulations and any special postings or publications set forth by the refuge manager.

ii. Canada goose and snow goose hunting will be permitted 7 days per week during the refuge's set hunting dates. Hunting hours are in accordance with New York State regulations for Canada goose and snow goose seasons.

iii. You must possess, carry, and present upon request to any law enforcement officer a valid daily hunt permit card (Migratory Bird Hunt Report, FWS Form 3–2361). We also require you to return the daily hunt permit card at the end of hunting or at the end of the day. You can obtain a permit at the Hunter Check Station on State Route 89 and return it to the same location; obtaining a permit will be on a first-come, first-served basis each hunt day until the day's permits are all taken.

B. Upland Game Hunting. We allow hunting of wild turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must carry and present upon request to any law-enforcement officer a valid daily hunt permit card (Big/Upland Game Hunt Application, FWS Form 3–2356). We also require you to return the daily hunt permit card at the end of hunting or at the end of the day. You can obtain a permit at the Hunter Check Station on State Route 89 and return it to the same location; obtaining a permit during the fall season will be on a first-come, first-served basis each hunt day until the day's permits are all taken.

2. We only allow hunting from legal sunrise to legal sunset during the fall season and from ½ hour before legal sunrise to noon during the youth hunt weekend. We prohibit night hunting.

3. We allow hunting within the New York State fall turkey season. We prohibit hunting during the New York State spring turkey season.

4. We allow youth hunting during the New York State youth wild turkey hunt weekend, depending on whether mentors for youth hunters are available. Participants must make a reservation to hunt; each year, the refuge manager will set the date and time that we will accept reservations by phone. The reservation phone number is (315) 568–4136.

5. Youth hunters and their mentors must attend an orientation program conducted by refuge staff.

6. You may possess only approved nontoxic shot for hunting (see § 32.2(k)) while in the field if hunting with a shotgun. The refuge manager reserves the right to restrict hunting implements beyond State restrictions based on hunter satisfaction and visitor safety.

7. We prohibit hunting with dogs.

8. You may use portable blinds and decoys, but you must remove all equipment (see § 27.93 of this chapter) at the conclusion of each day.

9. We prohibit parking and walking along the Wildlife Drive for the purpose of hunting, unless otherwise posted by refuge personnel.

10. We prohibit use of all-terrain vehicles (ATVs) (see § 27.31(f) of this chapter), dirt bikes, bicycles, snowmobiles, and watercraft for the purpose of turkey hunting.

C. * * *

11. Hunting weapon restrictions follow New York State regulations; successful harvest with a bow or other hunting weapon during firearms season requires use of a firearms season tag. The refuge manager reserves the right to restrict hunting implements beyond State restrictions based on hunter satisfaction and visitor safety.

* * * * *

■ 26. Amend § 32.52, the entry for Pocosin Lakes National Wildlife Refuge, by:

■ a. Revising paragraphs A.4 and A.9;

■ b. Removing paragraphs A.12 and B.9;

■ c. Revising paragraphs C.2 and C.5;

■ d. Removing paragraph C.8; and

■ e. Redesignating paragraph C.9 as C.8.

The revisions read as follows:

§ 32.52 North Carolina.

* * * * *

Pocosin Lakes National Wildlife Refuge

A. * * *

4. We open the refuge for daylight use only (½ hour before legal sunrise to ½ hour after legal sunset), except that we allow hunters to enter and remain in hunting areas from 2 hours before legal sunrise until 2 hours after legal sunset when we allow hunting in those areas.

* * * * *

9. You may possess only approved nontoxic shot (see § 32.2(k)) while migratory game bird hunting.

* * * * *

C. * * *

2. You may hunt turkey only if you carry a valid permit (General Activities Special Use Permit Application, FWS Form 3–1383–G). These permits are valid only for the dates and areas shown on the permit. We require an application and a fee for those permits and hold a drawing, when necessary, to select the permittees. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting turkeys west of Evans Road and on the Pungo Unit.

* * * * *

5. We allow hunters to take feral hogs in any area that is open to hunting deer using only those weapons authorized for taking deer. On the Frying Pan tracts, we also allow hunters to take feral hogs, using only those weapons authorized for taking deer, whenever we open those tracts to hunting any game species with firearms.

* * * * *

■ 27. Amend § 32.53 by:

■ a. Under the entry Arrowwood National Wildlife Refuge:

■ i. Revising paragraphs C.2, C.5, D.2, and D.3;

■ ii. Removing paragraphs D.4, D.5, and D.6; and

■ iii. Redesignating paragraphs D.7 through D.9 as D.4 through D.6, respectively;

■ b. Revising paragraph B introductory text and paragraphs B.3 and C.6 under the entry Des Lacs National Wildlife Refuge;

■ c. Revising paragraphs B and C under the entry Lake Zahl National Wildlife Refuge; and

■ d. Revising paragraphs B and C under the entry Lostwood National Wildlife Refuge.

The revisions read as follows:

§ 32.53 North Dakota.

* * * * *

Arrowwood National Wildlife Refuge

* * * * *

C. * * *

2. We allow deer hunting on the refuge during the State Youth Deer Season except in select closed areas as posted.

* * * * *

5. We prohibit permanent tree stands. We allow temporary tree stands, blinds, and game cameras for daily use; you must remove them by the end of the day. You may clamp, rope, or chain stands, steps, and cameras to trees; you may not nail, wire, screw, or bolt them to trees (see § 32.2(i)).

* * * * *

D. * * *

2. We allow shore fishing, archery, and spearfishing along major road rights-of-way and interior portions of the refuge and by-pass channel during the entire State fishing season. We only allow walk-in access, except in designated areas.

3. We allow ice fishing and dark house spearfishing. We allow fish houses, cars, and trucks on the ice as conditions allow. You may leave fish houses on the ice overnight until March 15; after March 15 you must remove fish houses from the refuge before leaving for the day.

* * * * *

Des Lacs National Wildlife Refuge

* * * * *

B. * * *. You may hunt sharp-tailed grouse, Hungarian partridge, turkey, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

* * * * *

3. Upland game bird season opens on the day following the close of the regular deer gun season through the end of the State season.

* * * * *

C. * * *

6. Conditions B6 through B9 apply.

* * * * *

Lake Zahl National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of sharp-tailed grouse, Hungarian partridge, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We open the refuge daily from 5 a.m. to 10 p.m.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. Upland game bird season opens on the day following the close of the regular deer gun season through the end of the State season.

4. You may use hunting dogs to retrieve upland game. Dogs must be under your direct control at all times.

5. You may only enter the refuge by foot.

6. We prohibit the use of snowmobiles, all-terrain vehicles (ATVs), off-highway vehicles (OHVs), utility-type vehicles (UTVs), bicycles, or similar vehicles on the refuge.

7. We prohibit the use of horses, mules, or similar livestock on the refuge during all hunting seasons.

C. Big Game Hunting. We allow deer hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B5 through B7 apply.

2. You may only use portable tree stands and ground blinds. We prohibit leaving stands and blinds overnight (see § 27.93 of this chapter). We prohibit driving nails, screws, spikes, or other objects into a tree or otherwise injuring a tree (see § 32.2(i)).

3. We prohibit entry to the refuge before 12 p.m. (noon) on the first day of the respective archery, gun, or muzzleloader deer hunting season.

4. We prohibit the use of flagging, trail markers, paint, reflective tacks, or other types of markers (see § 27.93 of this chapter).

5. We prohibit the use of trail cameras.

* * * * *

Lostwood National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of sharp-tailed grouse, Hungarian partridge, and ring-necked pheasant on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We open the refuge daily from 5 a.m. to 10 p.m.

2. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

3. We prohibit upland game hunting on the portion of the refuge south of Highway 50 during regular deer gun season.

4. We allow upland game hunting on the portion of the refuge north of Highway 50 on the day following the close of the regular deer gun season through the end of the State season.

5. You may use hunting dogs to retrieve upland game. Dogs must be under your direct control at all times.

6. You must comply with all "Closed to Hunting" signs.

7. You may only enter the refuge by foot.

8. We prohibit the use of snowmobiles, all-terrain vehicles (ATVs), off-highway vehicles (OHVs), utility-type vehicles (UTVs), bicycles, or similar vehicles on the refuge.

9. We prohibit the use of horses, mules, or similar livestock on the refuge during all hunting seasons.

C. Big Game Hunting. We allow deer hunting on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 and B6 through B9 apply.

2. You may only use portable tree stands and ground blinds. We prohibit leaving stands and blinds overnight (see § 27.93 of this chapter). We prohibit driving nails, screws, spikes, or other objects into a tree or otherwise injuring a tree (see § 32.2(i)).

3. We prohibit entry to the refuge before 12 p.m. (noon) on the first day of the respective archery, gun, or muzzleloader deer hunting season.

4. We prohibit the use of flagging, trail markers, paint, reflective tacks, or other types of markers (see § 27.93 of this chapter).

5. We prohibit the use of trail cameras.

* * * * *

■ 28. Amend § 32.55, the entry for Washita National Wildlife Refuge, by revising paragraphs A.1, A.2, and C to read as follows:

§ 32.55 Oklahoma.

* * * * *

Washita National Wildlife Refuge

A. * * *

1. We require permits (signed brochure) and payment of a fee to hunt goose, duck, and sandhill crane.

2. Goose, duck, and sandhill crane hunters must hunt from designated pit blinds.

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer, feral hog, and Rio Grande wild turkey on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow deer and feral hog hunting during the special refuge season in accordance with the refuge hunt information sheet. We will hold turkey hunts during the State spring turkey season.

2. We allow shotguns and lawful archery equipment for turkey hunting.

3. You must obtain a refuge hunt permit from the State and pay a fee (fee waived for youth hunters and mentors during the youth hunt).

4. You must check in and out of hunt areas daily at the refuge office or check station.

5. You must take bagged deer, hog, and/or turkey to the refuge check station.

6. We will determine bag limits on deer and turkey annually.

7. We prohibit the use of bait (see § 32.2(h)).

7. A non-hunting mentor age 21 or older must accompany, and be in the immediate presence of, youth hunters participating in the youth hunt. Youth hunters must be age 17 or younger. Both youth hunters and mentors must wear hunter orange clothing meeting or exceeding the minimum State requirements.

8. We prohibit using handguns for hunting.

* * * * *

■ 29. Amend § 32.56 by:

■ a. Revising paragraph A.8 under the entry Bandon Marsh National Wildlife Refuge;

■ b. Revising paragraphs A.5, A.6, and A.7 under the entry Lower Klamath National Wildlife Refuge;

■ c. Removing paragraph A.6 under the entry Nestucca Bay National Wildlife Refuge; and

■ d. Adding paragraph A.8 under the entry Siletz Bay National Wildlife Refuge.

The revisions and addition read as follows:

§ 32.56 Oregon.

* * * * *

Bandon Marsh National Wildlife Refuge

A. * * *

8. You may enter posted retrieval zones while retrieving downed birds and when traveling to and from the hunting areas. We prohibit discharging firearms while in a retrieval zone.

* * * * *

Lower Klamath National Wildlife Refuge

A. * * *

5. You may not set decoys in retrieving zones.

6. We prohibit the use of air-thrust and water-thrust boats.

7. You may possess only approved nontoxic shot while in the field (see § 32.2(k)).

* * * * *

Siletz Bay National Wildlife Refuge

A. * * *

8. You may enter posted retrieval zones while retrieving downed birds and when traveling to and from the hunting areas. We prohibit discharging firearms while in a retrieval zone.

* * * * *

■ 30. Amend § 32.60 by:

■ a. Under the entry Cape Romain National Wildlife Refuge:

■ i. Revising paragraphs B.11, B.15, D.11, and D.12; and

■ ii. Adding paragraphs D.14, D.15, and D.16;

■ b. Under the entry Carolina Sandhills National Wildlife Refuge:

■ i. Revising paragraphs A.1, A.3, and A.5 through A.9;
■ ii. Adding paragraph A.10;
■ iii. Revising paragraph B.1 and C.1;
■ iv. Removing paragraph C.11;
■ v. Redesignating paragraphs C.13 through C.19 as C.11 through C.17, respectively; and
■ vi. Revising paragraph D.9;
■ c. Revising paragraphs B, C, and D under the entry Santee National Wildlife Refuge; and
■ d. Revising the entry for Waccamaw National Wildlife Refuge.

The additions and revisions read as follows:

§ 32.60 South Carolina.

* * * * *

Cape Romain National Wildlife Refuge

* * * * *

B. * * *

11. We prohibit camping on the refuge except for designated archery hunters on Bulls Island and individuals obtaining a Special Use Permit (FWS Form 3–1383–G) from the refuge manager.

* * * * *

15. We prohibit overnight parking at Garris Landing, except for archery hunters during the designated refuge archery white-tailed deer season and individuals obtaining a Special Use Permit (FWS Form 3–1383–G) from the refuge manager. We require individuals parking vehicles at Garris Landing to obey all posted signs.

* * * * *

D. * * *

11. We prohibit the commercial transport of passengers to any refuge island for any purpose without a Special Use Permit (FWS Form 3–1383–C) from the refuge manager.

12. We prohibit feeding or harassing any marine mammal.

* * * * *

14. We prohibit any amphibious vehicle, hovercraft, airboat, or vessel from landing upon refuge islands.

15. We prohibit the use of any amphibious vehicle or vessel upon refuge lands or waters.

16. We prohibit any personal watercraft, as defined at 33 CFR 174.3, from landing upon refuge islands.

Carolina Sandhills National Wildlife Refuge

A. * * *

1. All hunters must carry a signed refuge General Hunt Permit (signed brochure) and government-issued picture identification.

* * * * *

3. Each youth hunter (younger than age 16) must remain within sight and normal voice contact and under supervision of an adult age 21 or older with a valid license and applicable permit. Each adult may supervise no more than two youth hunters. Each youth hunter must carry evidence of successful completion of a State-approved hunter-education course.

* * * * *

5. We prohibit the use or possession of alcoholic beverages while hunting on the refuge (see § 32.2(j)).

6. We prohibit discharge of weapons for any purpose other than to take or attempt to take legal game animals during established hunting seasons.

7. We prohibit the use of outdoor recreational vehicles (ORVs) except by mobility-impaired hunters with a Special Use Permit (FWS Form 3–1383–G) to use ORV in designated areas during specified hunts. Mobility-impaired hunters must have a State Disabled Hunting license in order to receive the Special Use Permit. Companions assisting disabled hunters must possess required State license(s) and refuge permit(s) and be listed on the Special Use Permit.

8. For hunting, you may possess shotguns with shot no larger than No. 5.

9. Legal shooting hours for September dove hunts are 12 p.m. (noon) to 6 p.m.

10. We prohibit the possession of more than 50 shotgun shells during the September dove hunts.

B. * * *

1. Conditions A1 through A7 apply.

* * * * *

C. * * *

1. Conditions A1 through A7 apply (with the following exception for condition A3: Each adult may supervise no more than one youth hunter).

* * * * *

D. * * *

9. We prohibit the use or possession of alcoholic beverages while fishing on the refuge (see § 32.2(j)).

* * * * *

Santee National Wildlife Refuge

* * * * *

B. Upland Game Hunting. We allow hunting of raccoon and opossum on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow hunters to use only weapons, firearms, and ammunition specifically authorized for each hunt.

2. All refuge hunters under age 16 must show proof of successfully completing a hunter-education/safety course. A properly licensed adult at least age 21 must directly supervise (within sight and normal voice contact) hunters under age 16. An adult may supervise only one youth.

3. We require hunters to possess a refuge hunt permit (signed refuge hunt brochure), a valid State hunting license, and government-issued picture identification while hunting. The refuge hunt permit is not valid until signed by the hunter.

4. Before hunting, each individual participant must obtain from a designated check station and display their completed User Information/Harvest Report Card (Big Game Harvest Report, FWS Form 3–2359) in plain view in their vehicle so that the required information is readable. After checking a harvested animal at a check station, the hunter must record species harvest information on reporting card. You must return all cards upon completion of the activity and before leaving the refuge.

5. You must check all animals taken on the refuge before removing the animal from the refuge and prior to 8:30 p.m. at the check station.

6. We require hunters to make a reasonable effort to retrieve wounded game. You must obtain permission from refuge personnel to enter a "No Hunting Zone" or "Closed Area" for any purpose.

7. We allow vehicles only on established roads marked open for vehicular traffic. You may travel roads marked "Closed to all vehicles" on foot or by bicycle. The speed limit for all roads is 15 mph. We prohibit all-terrain vehicles (ATVs) and utility-type vehicles (UTVs) or other off-road vehicles. You may park vehicles alongside roads but only in a manner that will not block gates, roads, or fire lanes or interfere with the normal flow of traffic.

8. Hunting firearms being transported in vehicles and boats during refuge hunts must be unloaded and cased or locked in a secure compartment (*e.g.,* toolbox or trunk). We define a loaded firearm as having ammunition in the chamber or magazine. Muzzleloaders will be considered unloaded if the percussion cap is not seated in the chamber.

9. We prohibit hunting with poison tip arrows (pods), exploding arrows, center fire rifles, and handguns (see § 32.2(g)).

10. We prohibit possession of bait, baiting, and/or hunting in the vicinity of bait (see § 32.2(h)).

11. We prohibit camping, overnight parking, fires, and littering (see §§ 27.95(a) and 27.94 of this chapter).

12. We prohibit the possession of remote photography, videography, or any other remote device and trail-monitoring/counting devices.

13. We prohibit entry beyond "Closed Area" or "No Hunting Zone" signs. We prohibit discharging weapons within, into, or across a "No Hunting Zone" or "Closed Area."

14. We prohibit discharging a firearm from, on, or across any refuge road, or designated refuge foot trail.

15. We prohibit hunting from within 100 feet (30 meters (m)) of any roadway, whether open or closed to vehicular traffic, or from or within 300 yards (270 m) of any designated hunter check station or residence.

16. We prohibit the use or possession of alcoholic beverages while hunting (see § 32.2(j)).

17. We prohibit man or dog drives, stalk hunting, and/or hunting from artificially pruned trees for deer and feral hogs.

18. We allow hunting on each refuge unit only within specified hunt periods and only for raccoon or opossum, and white-tailed deer (see paragraph C, Big Game Hunting, of this entry).

19. We allow unlimited harvest of feral hog as an incidental take while hunting during the day.

20. We will open hunting areas from 5 a.m. until 8:30 p.m. during designated hunt periods.

21. We allow use of dogs only for raccoon and opossum hunting. The dogs must wear a collar displaying the owner's name, address, and telephone number.

22. We allow take of raccoon and opossum only during night hunting from the hours of 6 p.m. to 6 a.m. We prohibit hunting on Saturday nights and Sunday nights. Special State regulations apply for night hunting.

23. We allow take of raccoon and opossum with a shotgun using nontoxic shot size no larger than #4 or a .22-caliber rimfire rifle. We prohibit possession of buckshot or slugs. We prohibit the use of all other weapons for hunting.

C. Big Game Hunting. We allow hunting of white-tailed deer on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions B1 through B20 apply.

2. We prohibit the use of dogs during deer hunts.

3. We prohibit night hunting of deer and feral hogs. On the refuge, nighttime is defined from ½ hour after legal sunset to ½ hour before legal sunrise.

4. We prohibit driving nails, screws, spikes, or other metal objects into a tree, and we prohibit hunting from a tree into which those objects have been driven (see § 32.2(i)).

5. We prohibit destroying or cutting vegetation (see § 27.51 of this chapter). We prohibit the possession of axes, saws, machetes, or other tools used for cutting vegetation on the refuge while scouting or hunting.

6. We prohibit trail flagging. You may use clothes pins with reflective tape/tack or commercially made reflective orange glow or trail clips to mark the path to the tree. You must mark all clips and pins with your full name, and you must remove them at the end of the hunt period. We will consider any clips or pins found without a hunter's name or any found after the end of a hunt period to be littering (see § 27.94 of this chapter), and we will remove them immediately.

7. We require hunters to wear an outer garment visible above the waist that contains a minimum of 500 square inches (3,226 square centimeters) of unbroken, solid fluorescent orange (hunter orange) material at all times during firearms and muzzleloader hunts. This does not apply to dove, raccoon, and turkey hunts.

8. Deer and feral hog hunting must occur from portable elevated hunting stands. A safety belt or harness must be used while using a hunting stand. We prohibit ground blinds. We allow only one stand per hunter, and each hunter must clearly mark stands with his or her full name, date, and phone number. We will confiscate any stands found without the hunter's name, date, and phone number marked on them.

9. We allow scouting on both the Pine Island and Cuddo Units during periods when these units are open to general public access. We allow vehicles only on roads designated as open for vehicular traffic. All other roads and trails are open to walk-in or bicycle traffic. We prohibit hunting weapons and dogs during scouting activities.

10. We will open access roads, closed to the general public for driving, only during each deer hunt and on the Friday, Saturday, and Sunday prior to each hunt.

11. You may place stands, clothes pins, or clips, only on open hunt areas on the Friday, Saturday, and Sunday immediately prior to each hunt (from 7 a.m. until 5 p.m.) and must remove them by 8:30 p.m. on the last day of each hunt period. We will confiscate any stands found outside of allowed periods.

12. We open the Plantation Islands (Cuddo Unit) to deer and feral hog hunting only from 5 a.m. until 2:30 p.m.

13. Shooting hours are from ½ hour before legal sunrise until ½ hour after legal sunset.

14. The refuge conducts one lottery draw hunt (Quota Deer Hunt Application, FWS Form 3–2354) for the Family, Friends, and Kids (Family Friendly) hunts conducted on the Bluff Unit of the refuge. Contact the refuge office for dates, application information, and more information about this special hunt opportunity.

15. We allow the use of non-motorized boats for accessing the unit's interior canals to inland areas open to hunting.

D. Sport Fishing. We allow fishing on the refuge in accordance with State regulations and subject to the following conditions:

1. A valid State fishing license, a signed refuge fishing permit (signed brochure), and government-issued picture identification must be in each angler's possession while fishing on the refuge. A signed refuge permit must be in each fisherman's possession while fishing on the refuge, except all recreational fishing boat operators are only required to have one refuge fishing permit per boat. A refuge fishing permit is not valid until signed.

2. We allow public fishing on all four refuge units. We open waters of Lake Marion within refuge boundaries for fishing 24 hours a day, except in areas posted as "Closed Areas" or closed for migratory bird management (sanctuaries). We allow fishing only on the inland ponds and canals during times the refuge units are open for general public access or as posted. We prohibit fishing at night, to include bank fishing, except by boat in Lake Marion.

3. Cantey Bay (Bluff Unit), Black Bottom (Cuddo Unit), and Savannah Branch (Pine Island Unit) are only open to public access, including boating and fishing, from March 1 through October 31.

4. We limit access to the interior freshwater canals and ponds to canoes or kayaks, or by foot or bicycle travel only. We prohibit use of internal combustion engines on interior ponds and canals.

5. We prohibit littering, camping and/or overnight parking, open fires, swimming or wading, collecting or searching for or taking of any items of antiquity, and overnight mooring of boats (see §§ 27.62, 27.94, and 27.95(a) of this chapter). We allow pets only in designated areas, and they must remain on a leash or within vehicles/vessels.

6. We prohibit fishing or boating within 100 feet (30 meters) of any nesting bird or bird rookeries within refuge boundaries.

7. We prohibit nighttime access to boat-launching areas.

8. We prohibit commercial fishing.

9. We prohibit attaching trotlines, bush/limb lines, fishing devices, signs,

or any other objects to trees, posts, or markers within refuge boundaries.

10. We prohibit shellfishing of all mollusks, including Asian clams.

11. We prohibit mooring or attaching boats to any refuge boundary marker, post, or navigational post within refuge waters.

12. We prohibit air-thrust boats, hovercraft, airboats, and personal watercraft (jet skis) within the waters of and/or boundary of the refuge.

* * * * *

Waccamaw National Wildlife Refuge

A. Migratory Game Bird Hunting. We allow hunting of duck, goose, dove, woodcock, and snipe on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must possess and carry at all times while hunting a signed, current refuge hunting regulations brochure, which serves as the hunt permit. The hunt permit is invalid until signed by the hunter.

2. Each youth hunter age 15 and younger must remain within sight, within normal voice contact, and under the supervision of an adult age 21 or older, except when participating in the Federal Youth Days waterfowl hunt, when the youth hunter must be under the supervision of an adult age 18 or older. We do not require youth hunters to have a hunter-education card for migratory gamebird hunting, but they must possess a signed refuge hunting regulations brochure. The supervising adult must comply with all State and Federal hunting license requirements and also possess a signed refuge hunting regulations brochure. Each supervising adult may supervise no more than two youths.

3. We allow waterfowl hunting only until 12 p.m. (noon) each Saturday and Wednesday during the State waterfowl season. Hunters may enter the refuge no earlier than 5 a.m. on hunt days and must be off the refuge by 2 p.m.

4. We allow scouting Monday through Friday during the waterfowl season. Hunters must be off the refuge by 2 p.m.

5. You may possess only approved nontoxic shot (see § 32.2(k)) while hunting all species of migratory birds on the refuge.

6. We prohibit permanent blinds (see § 27.93 of this chapter). Hunters must remove portable blinds and decoys at the end of each day's hunt.

7. We allow use of dogs only while hunting. We require dogs to wear a collar displaying the owner's name, address, and phone number.

8. We do not require hunter check-in and check-out, with the exception of special lottery hunts. There is no quota on the number of hunters for general hunting.

9. We prohibit discharge of weapons for any purpose other than to take or attempt to take legal game animals during established hunting seasons (see § 27.42(a) of this chapter).

10. We prohibit hunting on any unit for wildlife species not officially opened to hunting or posted as "No Hunting Zones." We prohibit entering any unit or area posted as "Closed."

11. We require individuals parking vehicles in the refuge to obey all posted signs.

12. Access into all refuge hunt areas for hunting and scouting is by foot, bicycle, or boat. We prohibit ATVs (see § 27.31(f) of this chapter) and air boats on the refuge.

B. Upland Game Hunting. We allow hunting of gray squirrel, raccoon, and opossum on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A2, and A8 through A12 apply.

2. We allow hunting only in designated areas and only on days designated annually by the refuge within the State season.

3. You may possess only nontoxic shot no larger than #2 in shotguns for hunting. We allow .22-caliber rimfire rifles.

4. We prohibit shooting any game from a boat except waterfowl.

5. We require the use of dogs for hunting raccoon and opossum.

6. The refuge prohibits upland game hunting during refuge Big Game Hunts.

C. Big Game Hunting. We allow hunting of white-tailed deer, feral hog, and turkey on designated areas of the refuge. The State of South Carolina does not classify feral hog as big game; however, for the purpose of these regulations, we include feral hog in the big game category. We allow big game hunting on the refuge in accordance with State regulations and subject to the following conditions:

1. Conditions A1, A8 through A12, B2 and B4 apply.

2. We only allow hunting for designated species on days designated annually by the refuge, within the State season and limits, and according to refuge unit-specific regulations annually listed in the refuge hunting regulations brochure.

3. We close areas open to hunting to the general public during big game hunts.

4. We allow archery, muzzleloading (black powder), rifles (centerfire larger than .22 caliber), and shotguns according to refuge unit-specific regulations.

5. We prohibit blow guns and drugged arrows (see § 32.2(g)). We allow muzzleloading rifles that use only a single projectile on the muzzleloader hunts. We prohibit buckshot, rimfire ammunition, and full-metal-jacketed military ammunition.

6. Access into all refuge hunt areas for hunting and scouting is by foot or boat. We may open some refuge roads on hunt days. We prohibit ATVs (see § 27.31(f) of this chapter) and air boats on the refuge.

7. We allow scouting all year during daylight hours except during the State waterfowl season. During the waterfowl season, the same regulations that apply to scouting for waterfowl (see condition A4) apply to scouting for big game species. We prohibit the use of trail cameras and other scouting devices.

8. Hunters may enter the refuge no earlier than 5 a.m. on hunt days and must leave the refuge no later than 1 hour after legal sunset.

9. We do not require hunter check-in and check-out, with the exception of special lottery hunts.

10. The refuge limit on antlered deer is one antlered buck per hunt session that must have at least three antler points on one side. We define a "point" as an antler projection of at least 1 inch (2.5 centimeters) or more in length. Hunters can harvest two antlerless deer per year during coinciding State doe days or by using personal doe tags.

11. You may take feral hogs during refuge deer hunts. There is no size or bag limit on hogs. We may offer special hog hunts during and after deer season to further control this invasive species. You must dispatch all feral hogs before removing them from the refuge.

12. We prohibit hunting on or within 100 feet (30 meters) of all routes marked as roads or trails on the hunt brochure map.

13. You must hunt deer and feral hog from an elevated hunting stand.

14. We allow only one portable tree stand per hunter, and you must clearly mark it with your full name and phone number. We prohibit placing deer stands on the refuge more than 3 days prior to the opening day of a hunting session. Hunters must remove stands from the refuge no later than 3 days after each refuge big game hunt (see § 27.93 of this chapter).

15. We allow hunters to use flagging to mark the site of hunter entry from roads or trails and again at the stand site. We allow hunters to use clothes pins with reflective tape between entry and stand sites to mark the route to the stand. You must label all pins with your

full name and remove them at the end of the hunt.

16. We require hunters to wear an outer garment visible above the waist that contains a minimum of 500 square inches (3,226 square centimeters) of solid, fluorescent-orange material at all times during big game hunts except for wild turkey.

17. We prohibit the use of organized drives, including the use of boats, as an aid in the taking or attempting to take big game species.

18. We prohibit possession of bait, distribution of bait, or hunting over a baited area (see § 32.2(h)).

19. We allow crossbows only during the big game hunting sessions, when we allow muzzleloaders and modern weapons. We may also allow crossbows during special hunts if determined to be appropriate.

20. Each youth hunter age 15 and younger must remain within sight, within normal voice contact, and under supervision of an adult age 21 or older, and must possess a signed refuge hunting regulations brochure. We do not require youth hunters who are sitting in the same hunting stand as the supervising adult to possess a hunter-education card. We require youth hunters who are sitting in a hunting stand by themselves to possess a valid hunter-education card. The supervising adult must comply with all State and Federal hunting license requirements and possess a signed refuge hunting regulations brochure. Each supervising adult may supervise a maximum of one youth.

21. We only allow deer and hog hunting on the uplands of Sandy Island during a special archery-only lottery hunt. Hunters must apply for lottery entry and are chosen by a random selection process. There is a quota on the number of hunters selected for this hunt.

22. We have special hunts for youth and mobility-impaired hunters on the Normandy Tract. You may obtain information about the drawing from the refuge office or Web site.

D. Sport Fishing. We allow fishing in accordance with State regulations.

■ 31. Amend § 32.61, the entry for Lake Andes National Wildlife Refuge, by revising paragraph D to read as follows:

§ 32.61 South Dakota.

* * * * *

Lake Andes National Wildlife Refuge

* * * * *

D. Sport Fishing. We allow sport fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must remove all boats, motor vehicles, fishing equipment, and other personal property, excluding ice houses, by the end of each day (see §§ 27.93 and 27.94 of this chapter).

2. We allow fishing on the Center and South units of Lake Andes.

* * * * *

■ 32. Amend § 32.62 by:

■ a. Under the entry Cross Creeks National Wildlife Refuge:

■ i. Revising paragraphs A.2, A.3, A.8, B.2, B.3, and B.8;

■ ii. Removing paragraph B.9; and

■ iii. Revising paragraphs C.4. and D.1;

■ b. Revising paragraphs A.6, B.1, B.4, and D.8 under the entry Hatchie National Wildlife Refuge; and

■ c. Under the entry Tennessee National Wildlife Refuge:

■ i. Revising paragraphs A.2, A.8, B.2, and B.9;

■ ii. Removing paragraph B.10; and

■ iii. Redesignating paragraph B.11 as B.10.

The revisions read as follows:

§ 32.62 Tennessee.

* * * * *

Cross Creeks National Wildlife Refuge

A. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

3. We set and publish season dates and bag limits annually in the Refuge Hunting and Fishing Regulations available at the refuge office.

* * * * *

8. Youth hunters under age 17 must remain in sight and normal voice contact with an adult hunter age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

B. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

3. We set and publish season dates and bag limits annually in the Refuge Hunting and Fishing Regulations available at the refuge office.

* * * * *

8. Each youth hunter under age 17 must remain within sight and normal voice contact of an adult age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

C. * * *

4. Each youth hunter younger than age 17 must remain within sight and normal voice contact of an adult age 21 or older. One adult hunter may supervise no more than one youth hunter.

* * * * *

D. * * *

1. We allow fishing on the refuge pools and reservoirs from March 16 through November 14 from ½ hour before legal sunrise to ½ hour after legal sunset.

* * * * *

Hatchie National Wildlife Refuge

A. * * *

6. Mourning dove, woodcock, and snipe seasons close during all deer archery, quota deer gun, and youth deer gun hunts. In the area west of Interstate 40 we follow the State seasons, except we close during youth deer gun and quota deer gun hunts.

* * * * *

B. * * *

1. Conditions A1 through A4, A6, and A8 through A12 apply.

* * * * *

4. We close all small game hunts during the refuge deer archery, quota, and youth gun hunts, except in the area west of Interstate 40, where small game reopens after the second quota deer gun hunt in accordance with State seasons.

* * * * *

D. * * *

8. We allow the use of nonmotorized boats and boats with electric motors only; we prohibit the use of gas and diesel motors on refuge lakes except in the waterfowl hunting area.

* * * * *

Tennessee National Wildlife Refuge

A. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must carry a valid refuge permit while hunting on the refuge.

* * * * *

8. Youth hunters under age 17 must remain in sight and normal voice contact with an adult hunter age 21 or older. One adult hunter may supervise no more than two youth hunters.

* * * * *

B. * * *

2. We require a refuge hunt permit (name and address) for all hunters age 17 and older. We charge a fee for all hunt permits. You must possess and carry a valid refuge hunt permit while hunting on the refuge.

* * * * *

9. Each youth hunter (under age 17) must remain within sight and normal voice contact and under supervision of an adult age 21 or older. One adult may supervise no more than two youth hunters.

* * * * *

■ 33. Amend § 32.63 by:

■ a. Revising paragraph A introductory text and paragraphs A.1 through A.4 under the entry Anahuac National Wildlife Refuge;

■ b. Revising paragraphs B.1 and C under the entry Buffalo Lake National Wildlife Refuge;

■ c. Under the entry Hagerman National Wildlife Refuge:

■ i. Revising paragraphs A.10, A.12, A.13, and A.14;

■ ii. Removing paragraphs A.15 through A.17; and

■ iii. Revising paragraphs B, C.1 through C.4, C.6, and D;

■ d. Under the entry Laguna Atascosa National Wildlife Refuge:

■ i. Revising paragraph C.7; and

■ ii. Adding paragraph C.19; and

■ e. Under the entry Lower Rio Grande Valley National Wildlife Refuge:

■ i. Revising paragraph A.6;

■ ii. Adding paragraph A.23; and

■ iii. Revising paragraphs C.1 and C.4.

The revisions and additions read as follows:

§ 32.63 Texas.

* * * * *

Anahuac National Wildlife Refuge

A. * * *. We allow hunting of goose, duck, coot, white-winged dove, mourning dove, Eurasian collared-dove, and rock pigeon on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. You must carry a current signed refuge hunting permit (signed brochure) while waterfowl hunting on all refuge hunt units.

2. Season dates for waterfowl will be concurrent with the State, except as specified in the refuge hunting permit (signed brochure).

3. For waterfowl hunting, you may enter the refuge hunt units no earlier than 4 a.m. Hunting starts at the designated legal shooting time and ends at 12 p.m. (noon). You must leave refuge hunt units by 12:30 p.m. For dove hunting, you may enter the refuge an hour before legal sunrise and must leave the refuge by ½ hour after legal sunset. We close refuge hunt units on Thanksgiving, Christmas, and New Year's Day.

4. For waterfowl hunting, we allow hunting in portions of the East Unit on Saturdays, Sundays, and Tuesdays during the regular waterfowl seasons. We require payment of a $10 per day or $40 per year to hunt on the East Unit. All hunters must check in and out through the check station when accessing the East Unit by vehicle. We will allow a limited number of parties to access the East Unit by vehicle. All hunters entering the East Unit through the check station will designate a hunt area on a first-come, first-served basis (special duck hunt areas will be assigned through a random drawing). We will require hunters to remain in an assigned area for that day's hunt. We allow hunters to access designated areas of the East Unit by boat from Jackson Ditch, East Bay Bayou, or Onion Bayou. We require hunters accessing the East Unit by boat from Jackson Ditch, East Bay Bayou, or Onion Bayou to pay the $40 annual fee. We prohibit access to the East Unit Reservoirs from Onion Bayou via boat. We prohibit the use of motorized boats on the East Unit, except on ponds accessed from Jackson Ditch via Onion Bayou. We prohibit motorized boats launching from the East Unit. For dove hunting, you are allowed to access and hunt the designated areas on the East Unit by vehicles via Farm Market Road 1985 only. Hunters are required to follow rules published annually by TPWD relating to the TPWD AHP.

* * * * *

Buffalo Lake National Wildlife Refuge

* * * * *

B. Upland Game Hunting. * * *

1. We require hunters to pay a fee and obtain a Special Use Permit (FWS Form 3–1383).

* * * * *

C. Big Game Hunting. We allow hunting of white-tailed deer, mule deer, and feral hogs on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We prohibit recreational shooting and target practice or any non-hunting discharge.

2. We prohibit shooting or hunting of all animals except deer and feral hogs during the hunt.

3. We prohibit any use of all-terrain vehicles (ATVs).

4. We prohibit the use of dogs for big game hunting.

5. We prohibit the use of horses.

6. We prohibit the use or possession of alcoholic beverages while hunting on refuge lands (see § 32.2(j)).

7. We prohibit the use of tree stands or any devices such as nails, tacks, and scaffolding used to climb trees, tripod types of blinds, or other elevated blinds.

8. You are not allowed on the refuge after dark except in designated camping areas.

9. We prohibit the use of silencers or any like device that alters the noise on a firearm.

10. Youth hunt:

i. We define youth hunters as ages 9 to 16 years of age. To participate in the youth hunt, youth hunters must be no younger than age 9 and no older than age 16 at the time they apply for a permit to hunt (see condition A.10.iv) and when the hunt occurs.

ii. A Texas-licensed, adult supervisor age 18 or older who has successfully completed a Hunter Education Certification Course ("adult supervisor") must accompany youth hunters. Adult supervisors born prior to September 2, 1971, are exempt from the hunter-education requirement.

iii. When hunting, each adult supervisor may supervise only one youth hunter. A youth hunter may have up to two supervisors.

iv. All youth hunters must carry a valid Special Use Permit (FWS Form 3–1383–G) when hunting. Special Use Permits are available at the refuge office.

v. You must provide proof of the youth hunter's or supervisor's successful completion of a State hunter-safety course to refuge staff at the time of the hunt or the youth hunter will not be allowed to hunt. Adult supervisors born prior to September 2, 1971, are exempt from the hunter-safety course requirement.

vi. When hunting, the adult supervisor must be within normal voice control of the youth hunter at all times.

vii. Adult supervisors are not allowed to hunt during the youth hunt.

11. We may close hunting areas at any time due to fire dangers, inclement weather, or other unforeseen circumstances.

* * * * *

Hagerman National Wildlife Refuge

A. * * *

10. We prohibit airboats, hovercraft, and personal watercraft (Jet Skis, wave runner, jet boats, etc.) year-round on refuge waters.

* * * * *

12. We prohibit all-terrain vehicles (ATVs).

13. We prohibit horses.

14. We prohibit glass containers.

B. Upland Game Hunting. We allow hunting of squirrel and rabbit in the months of February and September on designated areas of the refuge in accordance with State regulations and subject to the following conditions: Conditions A1 through A14 apply.

C. * * *

1. We require a limited hunt permit (name) for archery deer, feral hog, and spring turkey hunts. In partnership with Texas Parks and Wildlife Department, we allow a special youth hunt as listed on the refuge hunt information sheet. For additional information on how to apply, contact the refuge headquarters at 903–786–2826.

2. Conditions A2, A5 through A7, and A10 through A14 apply.

3. We restrict hunt participants for limited hunts to those drawn for and in possession of a limited hunt permit (name). The permits are nontransferable. Hunt dates and application procedures will be available annually at the refuge headquarters.

4. We allow limited hunts for feral hog, archery deer, and spring turkey. We allow muzzleloaders, bow and arrow, and shotguns for feral hog and spring turkey hunts. You may possess only lead-free, nontoxic (steel, bismuth, copper, or tungsten) bullets, slugs, and shot (00 buck for hogs, no shell larger than No. 4 shot size for turkey).

* * * * *

6. We limit each hunter to one stand, which the hunter may place on the refuge during the day preceding each hunt. You must remove all stands by legal sunset on the last day of each hunt.

* * * * *

D. Sport Fishing. We allow fishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. Lake Texoma and connected streams are open to fishing year-round. We require a valid State of Texas or Lake Texoma fishing license in accordance with State regulations.

2. Conditions A10, and A12 through A14 apply.

3. You may bank fish on Lake Texoma with pole and line, rod and reel, or hand line year-round.

4. We allow wade fishing in refuge ponds March 15 through October 1 annually from all areas except Refuge Road, Wildlife Drive, Plover Road, Tern Road, and Egret Road.

5. We allow fishing in refuge ponds March 15 through September 30 annually. We require a valid State of Texas or Lake Texoma fishing license in accordance with State regulations.

6. Anglers may not use any glass containers, plastic jugs, or plastic bottles as floats.

7. We prohibit discarding any type of fishing line.

8. You may only take bait for personal use while fishing in refuge waters in accordance with Texas State law. We prohibit removal of bait from the refuge for commercial sales or use.

9. We prohibit fishing from bridges.

10. We allow the use of bow and arrow to take nongame fish on refuge waters except from Refuge Road, Wildlife Drive, Plover Road, Tern Road, and Egret Road.

11. We prohibit limb line, throw lines, jug lines, seine nets, noodling, and yo-yos.

12. We prohibit taking frog, turtle, and mussel from refuge lands and waters (see § 27.21 of this chapter).

13. We prohibit taking any fish or bait for any purpose from refuge impoundments year-round.

14. We prohibit entry into refuge impoundments and ponds by any means (*i.e.,* foot, boat, other floating device) for any purpose year-round.

Laguna Atascosa National Wildlife Refuge

* * * * *

C. * * *

7. Hunting means and methods, including use of firearms, archery, and crossbows, will be in accordance with State regulations unless otherwise designated. We publish this information in the refuge hunting sheet.

* * * * *

19. Persons possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

* * * * *

Lower Rio Grande Valley National Wildlife Refuge

* * * * *

A. * * *

6. We require hunters to pay a fee to obtain a refuge hunt permit (signed brochure) and to possess and carry that permit at all times during your designated hunt period. Hunters must also display the refuge-issued vehicle placard (part of the hunt permit) while participating in the designated hunt period. Hunters, including youth hunters, must also have a valid hunting license, proof of hunter's education certification, and picture identification in order to obtain a refuge hunt permit and must possess the items listed in this condition (A6) while on the refuge hunt.

* * * * *

23. Persons, possessing, transporting, or carrying firearms on National Wildlife Refuges must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this chapter and specific refuge regulations in this part 32).

* * * * *

C. * * *

1. Conditions A4 through A13, and A16 through A23 apply.

* * * * *

4. Hunters must follow the Hunting Means and Methods of Firearms, Archery and Crossbows outlined in the Texas Wildlife and Parks Department's (TPWD's) regulations unless otherwise designated. We will publish changes from the TPWD regulations that are applicable to hunting on the refuge in the refuge hunting tear sheet, which is available at the refuge office.

* * * * *

■ 34. Amend § 32.64 by revising paragraph B.4 under the entry Ouray National Wildlife Refuge to read as follows:

§ 32.64 Utah.

* * * * *

Ouray National Wildlife Refuge

* * * * *

B. * * *

4. We allow turkey hunting for youth hunters only.

* * * * *

■ 35. Amend § 32.66 by:

■ a. Revising paragraph C.15 under the entry Back Bay National Wildlife Refuge; and

■ b. Under the entry Great Dismal Swamp National Wildlife Refuge:

■ i. Revising paragraph C.6;

■ ii. Removing paragraph C.7;

■ iii. Redesignating paragraph C.8 as C.7;

■ iv. Removing paragraph C.9;

■ v. Redesignating paragraphs C.10 and C.11 as C.8 and C.9, respectively; and

■ vi. Revising paragraph D.1.

The revisions read as follows:

§ 32.66 Virginia.

* * * * *

Back Bay National Wildlife Refuge

* * * * *

C. * * *

15. We prohibit use of tree stands except on Long Island (Zone 1).

* * * * *

Great Dismal Swamp National Wildlife Refuge

C. * * *

6. Persons possessing, transporting, or carrying firearms on the refuge must comply with all provisions of State and local law. Persons may only use (discharge) firearms in accordance with refuge regulations (see § 27.42 of this

chapter and specific refuge regulations in this part 32).

* * * * *

D. * * *

1. During daylight hours, we allow fishing in Lake Drummond and in the Feeder Ditch from boat, and from the piers at Washington Ditch and Interior Ditch.

* * * * *

■ 36. Amend § 32.67 by:

■ a. Under the entry Little Pend Oreille National Wildlife Refuge:

■ i. Revising paragraphs A.2 and B; and

■ ii. Removing paragraph C.3;

■ b. Revise the entry Nisqually National Wildlife Refuge to read, "Billy Frank Jr. Nisqually National Wildlife Refuge", moving the entry into alphabetical order within the section, and revising paragraph D; and

■ c. Revising paragraph A.3 under the entry Ridgefield National Wildlife Refuge.

The revisions read as follows:

§ 32.67 Washington.

* * * * *

Billy Frank Jr. Nisqually National Wildlife Refuge

* * * * *

D. Sport Fishing. We allow fishing and shellfishing on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow fishing from boats outside the Sanctuary Area and outside the Research Natural Area.
2. We prohibit bank fishing along the Nisqually River.
3. We prohibit fishing in any waters inside the Sanctuary Area.
4. We allow shellfishing on the tideflats. Access is by boat or by foot from the Luhr Beach Boat Launch. We prohibit tideflat access from Refuge Dike.
5. We prohibit boat launching on the refuge.

* * * * *

Little Pend Oreille National Wildlife Refuge

* * * * *

A. * * *

2. We allow hunting during approved State hunting seasons occurring from September through December. We prohibit hunting and discharging firearms during all other periods.

* * * * *

B. Upland Game Hunting. We allow hunting of upland game and other small game on designated areas of the refuge in accordance with State regulations and subject to the following conditions:

1. We allow hunting during approved State hunting seasons occurring September through December, and during the State spring wild turkey season. We prohibit hunting and discharge of firearms during all other periods.
2. During the State spring turkey season, we prohibit hunting of all species except wild turkey.
3. We prohibit raccoon hunting with dogs.
4. Condition A3 applies.

* * * * *

Ridgefield National Wildlife Refuge

A. * * *

3. We limit or prohibit hunting of dusky Canada goose in accordance with State regulations. The State defines dusky Canada goose as a dark-breasted Canada goose, as determined by a Munsell color chart 10 YR, 5 or less, with a culmen (bill) length of 40 to 50 millimeters (1.6 to 2 inches). In addition, we will close the refuge goose season early if the dusky Canada goose harvest reaches a quota adopted by the refuge.

* * * * *

Karen Hyun,

Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–15259 Filed 7–13–16; 8:45 am]

BILLING CODE 4333–15–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part IV

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1
Federal Acquisition Regulation; Federal Acquisition Circular 2005–89; Introduction, Small Business Improvements, OMB Circular Citation Update, FPI Blanket Waiver, Revision to Standard Forms for Bonds, Technical Amendments, and Federal Acquisition Circular 2005–89; Small Entity Compliance Guide; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2016–0051, Sequence No. 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–89; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2005–89. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC. The FAC, including the SECG, is available via the Internet at *http://www.regulations.gov.*

DATES: For effective dates see the separate documents, which follow.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to the FAR case. Please cite FAC 2005–89 and the specific FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2005–89

Item	Subject	FAR Case	Analyst
I	Small Business Subcontracting Improvements	2014–003	Uddowla.
II	OMB Circular Citation Update	2014–023	Hopkins.
III	FPI Blanket Waiver Threshold	2016–008	Uddowla.
IV	Revision to Standard Forms for Bonds	2015–025	Hopkins.
V	Technical Amendments.		

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–89 amends the FAR as follows:

Item I—Small Business Subcontracting Improvements (FAR Case 2014–003)

This final rule amends the FAR to implement SBA's final rule published at 78 FR 42391 on July 16, 2013. The rule will implement the statutory requirements set forth in section 1321 and 1322 of the Small Business Jobs Act of 2010, (Pub. L. 111–240), as well as other requirements aimed at improving subcontracting regulations to increase small business opportunities. This rule accomplishes the following:

(1) Requires prime contractors to make good faith efforts to utilize their proposed small business subcontractors during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. To the extent a prime contractor is unable to make a good faith effort to utilize its small business subcontractors as described above, the prime contractor is required to explain, in writing, within 30 days of contract completion, to the contracting officer the reasons why it was unable to do so.

(2) Authorizes contracting officers to calculate subcontracting goals in terms of total contract dollars in addition to the required goals in terms of total subcontracted dollars.

(3) Provides contracting officers with the discretion to require a subcontracting plan in instances where a small business rerepresents its size as an other than small business.

(4) Requires subcontracting plans even for modifications under the subcontracting plan threshold if said modifications would cause the contract to exceed the plan threshold.

(5) Requires prime contractors to assign (North American Industry Classification System (NAICS)) codes to subcontracts.

(6) Restricts prime contractors from prohibiting a subcontractor from discussing payment or utilization matters with the contracting officer.

(7) Requires prime contractors to resubmit a corrected subcontracting report within 30 days of receiving the contracting officer's notice of report rejection.

(8) Requires prime contractors to provide the socioeconomic status of the subcontractor in the notification to unsuccessful offerors for subcontracts.

(9) Requires prime contracts with subcontracting plans on task and delivery order contracts to report order level subcontracting information after November 2017.

(10) Facilitates funding agencies receiving small business subcontracting credit.

(11) On indefinite-delivery, indefinite-quantity contracts, allows the contracting officer to establish subcontracting goals at the order level (but not a new subcontracting plan).

This rule may have a positive economic impact on any small business entity that wishes to participate in the Federal procurement arena as a subcontractor.

Item II—OMB Circular Citation Update (FAR Case 2014–023)

This final rule amends the FAR to update outdated OMB Circular citation references. On December 26, 2013, the Office of Management and Budget (OMB) published new guidance at 2 CFR part 200 entitled Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, adopted by Federal agencies as a set of binding regulations that became effective December 26, 2014. This new guidance supersedes and streamlines requirements from OMB Circulars A–21, A–87, A–89, A–102, A–110, A–122, and A–133, as well as the guidance in Circular A–50 on Audit Followup. As such, this final rule replaces OMB citations in the FAR to the circulars cited above that have been superseded. The replacement of these outdated OMB citations in the FAR will have no impact on small businesses since the intent of the OMB guidance remains unchanged.

Item III—FPI Blanket Waiver Threshold (FAR Case 2016–008)

This final rule amends the FAR to increase the blanket waiver threshold for small dollar-value purchases from Federal Prison Industries (FPI) by Federal agencies from $3,000 to $3,500. No waiver is required to buy from an alternative source below $3,500. Customers may, however, still purchase from FPI at, or below, this threshold, if they so choose.

Item IV—Revision to Standard Forms for Bonds (FAR Case 2015–025)

This rule amends the FAR to revise five Standard Forms prescribed for contracts involving bonds and other financial protections. The revisions, aimed at clarifying liability limitations and expanding the options for organization types, are made to Standard Forms 24, 25, 25A, 34, and 35. These changes will minimize questions from industry to the contracting officer.

This final rule does not place any new requirements on small entities.

Item V—Technical Amendments

Editorial changes are made at FAR 4.1801, 4.1803, 52.204–16, 52.204–17, 52.204–18, 52.204–20, and 52.212–3.

Dated: June 30, 2016.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2005–89 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2005–89 is effective July 14, 2016 except for item I which is effective November 1, 2016, and items II, III, and IV, which are effective August 15, 2016.

Dated: July 1, 2016.

Claire M. Grady,

Director, Defense Procurement and Acquisition Policy

Dated: July 1, 2016.

Jeffrey A. Koses,

Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

Dated: June 29, 2016.

William G. Roets,

Acting Assistant Administrator, Office of Procurement National Aeronautics and Space Administration.

[FR Doc. 2016–16244 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 2, 15, 19, and 52

[FAC 2005–89; FAR Case 2014–003; Item I; Docket No. 2014–0003; Sequence No. 1]

RIN 9000–AM91

Federal Acquisition Regulation; Small Business Subcontracting Improvements

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement regulatory changes made by the Small Business Administration, which provide for a Governmentwide policy on small business subcontracting.

DATES: *Effective:* November 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, at 703–605–2868 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–89, FAR Case 2014–003.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 80 FR 32909 on June 10, 2015. The proposed rule discussed regulatory changes made by the Small Business Administration (SBA) in its final rule published at 78 FR 42391, on July 16, 2013, concerning small business subcontracting. SBA's final rule implements the statutory requirements in sections 1321 and 1322 of the Small Business Jobs Act of 2010 (Pub. L. 111–240), as well as other changes aimed at improving subcontracting regulations to increase small business opportunities. The changes being implemented in this final rule include the following:

(1) Requiring prime contractors to make good faith efforts to utilize their proposed small business subcontractors during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. To the extent a prime contractor is unable to make a good faith effort to utilize its small business subcontractors as described above, the prime contractor is required to explain, in writing, within 30 days of contract completion, to the contracting officer the reasons why it is unable to do so.

(2) Authorizing contracting officers to calculate subcontracting goals in terms of total contract dollars in addition to the required goals in terms of total subcontracted dollars.

(3) Providing contracting officers with the discretion to require a subcontracting plan in instances where a small business rerepresents its size as an other than small business.

(4) Requiring subcontracting plans even for modifications under the subcontracting plan threshold if said modifications would cause the contract to exceed the plan threshold.

(5) Requiring prime contractors to assign North American Industry Classification System (NAICS) codes to subcontracts.

(6) Restricting prime contractors from prohibiting a subcontractor from discussing payment or utilization matters with the contracting officer.

(7) Requiring prime contractors to resubmit a corrected subcontracting report within 30 days of receiving the contracting officer's notice of report rejection.

(8) Requiring prime contractors to provide the socioeconomic status of the subcontractor in the notification to unsuccessful offerors for subcontracts.

(9) Requiring prime contracts with subcontracting plans on task and delivery order contracts to report order level subcontracting information after November 2017.

(10) Funding agencies receiving small business subcontracting credit.

(11) On indefinite-delivery, indefinite-quantity contracts, the contracting officer may establish subcontracting goals at the order level (but not a new subcontracting plan).

Twenty-seven respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments received and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes

This final rule makes the following significant changes from the proposed rule:

- FAR 19.703(a)(2), 52.219–8(d), 52.219–9(c)(2), and 52.219–9 Alternate IV (c)(2)—language has been revised to neither specify an order of precedence nor prescribe how subcontractor representations should be obtained by a prime contractor.
- FAR 19.704(a)(10)(iii), 52.219–9(d)(10)(iii), and 52.219–9 Alternate IV (d)(10)(iii)—language has been revised to require order-level reporting on single-award, indefinite delivery, indefinite quantity contracts intended for use by multiple agencies in addition to multiple-award contracts in use by multiple agencies and to clarify that the order-level reporting would be required after November 2017, which is when Electronic Subcontracting Reporting System (eSRS) will be ready to accommodate the requirement.
- FAR 19.704(a)(10)(iv)(A) and (B)—language has been revised to remove the reasons for the rejection of an Individual Subcontract Report or Summary Subcontract Report, since those reasons are not an exhaustive list.
- FAR 19.704(a)(14), 52.219–9(d)(13), and 52.219–9 Alternate IV (d)(13)—language has been revised to match surrounding paragraphs on contractor providing "assurances".
- FAR 19.704(c)—language has been added to clarify that the requirement to have separate goals for the base and option years will only apply to goals based on total subcontract value.
- FAR 19.705–1 and 19.705–2—language has been added to clarify that contracting officers may only establish subcontracting goals at the order level, not subcontracting plans at the order level.
- FAR 19.705–2(b)(3)—language has been revised to encompass services, as well as supplies.
- FAR 52.219–9(d)(3) and (e)(7)—language has been revised to clarify that the contractor is to assign NAICS codes and corresponding size standards to all subcontracts, not list NAICS codes in subcontracting plans.

B. Analysis of Public Comments

1. Support for the Rule

Comment: Six respondents supported the overall changes and clarifications contemplated in the proposed rule. Among the positive changes noted by these respondents were the clarification of the subcontract reporting process, clarification of the HUBZone certification requirements, clarification of the requirement for contractors to notify unsuccessful offerors for subcontracts, and convenience afforded by allowing contractors to accept small business size and status certifications made in the System for Award Management (SAM). Other respondents noted that the clarification of what it means to "use" a small business concern when preparing a bid or proposal ensures that contractors can reasonably identify situations where the requirement applies and ensure proper notification is given.

Response: The Councils acknowledge these areas of agreement.

Comment: One respondent commented that they concurred with the clarification that a change in size status does not change the terms and conditions of a contract.

Response: The Councils acknowledge this comment; however, it is important to note that the contracting officer does have discretionary authority to require a subcontracting plan if the contractor rerepresents that its size status has changed from small to other than small.

2. Requirement for a Subcontracting Plan

a. Subcontracting Opportunities

Comment: Three respondents commented that the rule provides a contracting officer the authority to require a subcontracting plan from a prime contractor in two situations: when a prime contractor that was a small business concern at contract award recertifies as an other than small business concern (FAR 19.301–2(e)); and when a modification increases the total dollar value of a contract above the subcontracting plan threshold (FAR 19.702(a)(3)). The respondents explained that in certain situations under these circumstances, requiring the creation of a subcontracting plan would be administratively burdensome and provide few substantive subcontracting opportunities. As examples of when a subcontracting plan may not be appropriate, the respondents mention the following situations: contract performance is under way and the prime contractor has pre-existing exclusive supplier agreements with subcontractors; there are very few remaining or additional subcontracting opportunities; or the performance of the contract is almost complete. One of the respondents suggested providing the contracting officer additional guidance on when it is appropriate to require the submission of a subcontracting plan during contract performance. All of the respondents recommended the addition in the rule of the word "significant" before "subcontracting opportunities" at 19.702(a)(3) ". . . if the contracting officer determines that subcontracting opportunities exist."

Response: The rule provides the contracting officer authority to require the submission of a subcontracting plan under the circumstance noted. Specifically, at FAR 19.301–2(e), "the contracting officer may require a subcontracting plan . . . if a prime contractor's size status changes from small to other than small as a result of a size rerepresentation." At FAR 19.702, the mandatory requirement for submission of a subcontracting plan only happens "if the contracting officer determines that subcontracting opportunities exist." The rule contains language at FAR 19.705–2(b) that provides general guidance to contracting officers on how to determine whether subcontracting possibilities exist in the circumstances noted in the comment.

It would not be feasible in the final rule to include every possible factor that a contracting officer will need to consider in determining whether subcontracting opportunities exist, because these conditions will vary from acquisition to acquisition. Factors such as the remaining ceiling amount on the contract, effect on current prime contractor subcontractor agreements, amount of work ultimately going to the prime contractor's subcontractors that are small business concerns can all weigh heavily in this decision. As such, the language in the rule remains unchanged.

b. Treatment of Options

Comment: One respondent recommended the words "or an option is exercised" be deleted from paragraph (e) of FAR 19.705–2. Options are addressed in the initial subcontracting plan and whatever subcontracting possibilities that exist are defined in the initial plan. Requiring amendment of a plan whenever an option is exercised is redundant and adds cost and administrative burden, with little benefit.

Response: The Councils reviewed the area of the rule identified by the respondent to ensure that the appropriate requirements were being applied to subcontracting. The rule already reflects a revision to the existing FAR text to clarify that the goals shall be adjusted to reflect any new subcontracting opportunities that were not envisioned at the time of contract award, not as a requirement to negotiate a new goal each time an option is exercised. The final rule adds language at FAR 19.705–2(e) that the opportunities were not envisioned at the time of contract award.

c. Clarify When a Subcontracting Plan is not Required

Comment: One respondent recommended clarification to FAR 19.702(b)(4) while this rule is being finalized. The respondent commented that FAR 19.702(b)(4) is poorly worded and that a literal interpretation would be that, in order for the exception to apply, the contract modification would have to be within the general scope of the contract AND the contract modification would have to not include FAR clause 52.219–8. The respondent understands that this is not the intent and recommended restructuring the sentence to read "For contract modifications if (1) the contract modification is within the scope of the contract, and (2) the contract being modified does not contain the clause at 52.219–8, Utilization of Small Business Concerns."

The respondent also mentioned that by moving the language currently at FAR 19.705–2(c) to FAR 19.705–2(c)(2), it now gives the impression that the approval requirement for not including a subcontracting plan only applies when a modification increases the total contract dollars above the subcontracting plan threshold.

Response: The Councils reviewed the areas of the rule identified by the respondent and have amended the FAR in the final rule at FAR 19.702(b)(4), 19.705–2(c), and 19.705–2(f).

d. When a Small Business Rerepresents as Other Than Small

Comment: One respondent recommends that when a prime contractor's size changes from small to other than small as a result of rerepresentation, the contracting officer should be required to request a subcontracting plan.

The respondent further stated that Government contractors are consolidating and contract opportunities for small firms are decreasing as large businesses are acquiring small businesses, and as such when small businesses become other than small, a subcontracting plan should be required (particularly for indefinite-delivery, indefinite-quantity contracts with more than two years remaining).

Response: SBA's final rule grants contracting officers the discretion to require a subcontracting plan if size changes as a result of size rerepresentation.

3. Goals in Terms of Total Contract Dollars

Comment: A number of respondents expressed concern that the new requirement at FAR 19.704(a)(2) allowing contracting officers to require the contractor to establish subcontracting goals both in terms of the total dollars planned to be subcontracted and now also in terms of the total contract dollars will lead to confusion. Three respondents were strongly opposed to this approach, since the goals based on total contract value would be lower than the goals based on total planned subcontracting dollars, allowing a contracting officer to unfairly penalize a contractor that chose to perform the work using its own internal resources. One respondent remarked that the requirement for contractors to establish small business goals based on total contract dollars would be subject to protest and was contrary to the SBA's regulations. Two other respondents stated that the requirement for contractors to establish goals based on total subcontract dollars and total contract dollars should be mandatory.

Response: The Councils realize that this new requirement may entail additional effort on the behalf of contractors and the Government; however, many contracting officers have already established subcontracting goals in terms of total contract dollars as a means of obtaining additional insight into the contractor's subcontracting performance, and it has proven to be an effective management tool. As set forth in the proposed rule, the use of this approach is discretionary, not mandatory, and it is not intended to dissuade contractors from making normal make or buy decisions, or other prudent business choices.

Establishing two sets of subcontracting goals may not work in all situations, nor would it be beneficial for either the Government or the contractor to establish unrealistic goals. This is why contracting officers will need to carefully consider using this approach on a case-by-case basis, factoring in the unique characteristics of the acquisition at hand and the results of market research. In addition, although the Councils cannot predict the outcome of any solicitation in terms of the likelihood that it will be protested, this rule is fully consistent with SBA's regulations at 13 CFR 125.3(a)(2). Finally, to change the decision to require goals based on total contract dollars from discretionary to mandatory is beyond the scope of this rule.

Comment: One respondent wanted to know if the definition for total contract dollars at FAR 19.701 and clause 52.219–9(b) included the maximum quantity (or ceiling price) of an indefinite quantity contract, and asked that this be clarified in the rule. This respondent remarked that the definition for total contract dollars. . .

> "total contract dollars means the final anticipated dollar value, including the dollar value of all options 19.701"

. . . was inconsistent with the requirement to have separate goals for the base and option years. Further, basing a goal on the total contract value would likely place the contractor at a great disadvantage should the contract options not be exercised.

Response: The definition for total contract dollars includes the maximum or ceiling price for an indefinite delivery contract. The requirement to have overall goals encompassing the entire contract, including options, is consistent with SBA's regulations, and as noted, this rule amends the FAR to reflect SBA's regulations. However, the Councils have revised the rule at FAR 19.704(c) to clarify that the requirement to have separate goals for the base and option years will only apply to goals based on total subcontract value.

4. Assigning NAICS Codes to Subcontracts

Comment: Several respondents commented on the requirement in the proposed rule that prime contractors must identify in the subcontracting plan the NAICS code and corresponding size standard of each subcontract with a small business concern. A number of these respondents commented that due to the fact that contractors identify potential subcontracts after the award of the prime contract (particularly in the case of indefinite delivery, indefinite quantity contracts), it is possible that the NAICS codes and size standards projected in the subcontracting plan would be inaccurate and impossible to estimate. Other respondents commented that identifying the NAICS codes for all procurements would be administratively burdensome, and may result in excessively lengthy subcontracting plans. It was also noted that this burden has the potential to harm small business participation rather than enhance it. Numerous alternative approaches to the proposed rule were suggested.

Response: The Councils have revised the rule at FAR clause 52.219–9 to reflect the requirement from SBA's final rule, which directs the contractor to assign NAICS codes and corresponding size standards to all subcontracts, not to list NAICS codes in subcontracting plans.

Comment: One respondent recommended that at FAR clause 52.219(c)(2)(i)(B), the small business represent that the NAICS code is current, accurate, and complete as of the date of the offer for the subcontract, in addition to its size and status representation.

Response: The Councils did not adopt this suggestion in the final rule, since it is the responsibility of the contractor to accurately assign the proper NAICS code to the subcontract.

5. Subcontractor Representations

a. General

Comment: One respondent inquired where to find guidance regarding accepted practices for small business self-certification, auditing of small business certifications, and agency enforcement responsibilities.

Response: Subpart 19.3 of the FAR provides guidance for required small business representations in connection with Federal prime contracts. In addition, SBA's regulations at 13 CFR parts 121, 124, 125, 125, and 127 provide detailed information covering the small business certification procedures, audits, and enforcement.

Comment: One respondent commented that contractors should be allowed to accept the written representation from potential subcontractors, regardless of whether or not the offeror was registered in SAM.

Response: The FAR rule allows the prime contractor, under specific conditions, to accept size and socioeconomic status representations either from SAM or by written representation. However, the final rule has been revised to clarify there is no order of precedence for either method of acceptance, and to clarify that prime contractors are prohibited from requiring the use of SAM for the purposes of representing size or socioeconomic status.

Comment: A few respondents commented that the requirement to have a current representation each time an offer is made on a subcontract, including purchase orders between a prime contractor and a vendor, would be burdensome. Two respondents recommended that the rule be revised to make it acceptable for a contractor to obtain small business size representations on an annual basis, since small businesses are required to annually update their small business status, and the subcontractor should be obliged to promptly update any information in the event of a change.

Response: The requirement for a concern to represent its eligibility status when submitting an offer is not new; the proposed rule merely added guidance by giving prime contractors the option to accept either a subcontractor's self-certification in SAM or a written representation. With regard to obtaining the small business representation on an annual basis, the respondent's recommendation is not in keeping with SBA's regulations and, therefore, was not adopted by the Councils. SBA's regulations at 13 CFR 121.411(b) require that a subcontractor must qualify and self-certify as a small business at the time it submits its offer as a small business subcontractor.

Comment: Two respondents generally remarked and implied, respectively, that the requirement to make a size and socioeconomic representation on every offer was burdensome.

Response: The respondents' comments are noted; however, the representation requirement is in keeping with SBA's regulations. SBA's regulations at 13 CFR 121.411(b) require that a subcontractor must qualify and self-certify as a small business at the time it submits its offer as a small business subcontractor.

b. Written Representation Versus SAM Representation

Comment: A few respondents questioned whether the proposed rule should go so far as to only accept a subcontractor's written representation of its size and socioeconomic status if the contractor ascertained that the small business was not registered in SAM. They pointed out that this requirement was inconsistent with the SBA's regulations and placed unnecessary burdens on the contractor.

Response: There is no order of precedence in choosing whether to accept the small business subcontractor's representation through SAM or by a direct written response; both methodologies are equally acceptable. The rule has been revised to clarify that the contractor may accept either the subcontractor's written representation or its self-certification in SAM with equal assurance.

Comment: One respondent remarked that SBA's final rule referred to relying on subcontractor representations in SAM for the purpose of "maintaining a small business source list," and concluded this would foreclose reliance on SAM for uses other than maintaining a source list. For this reason, the respondent recommended deleting the proposed revision at FAR clause 52.219–8(d)(2) to allow contractors the flexibility to rely on SAM if they so choose.

Response: The SBA rule establishes that SAM may be used for both purposes. However, the final rule is revised to clarify that a contractor has the flexibility to rely on SAM if they so choose.

c. Maintaining "Safe Harbor"

Comment: Two respondents questioned whether the "safe harbor" afforded to a prime contractor for accepting a firm's written representation of its size or socioeconomic status in connection with a subcontract, extended to electronic representations. One respondent suggested that FAR 4.502(d) be amended to allow contractors to accept electronically signed representations.

Response: The Councils did not adopt the change suggested by the respondent, but have amended the FAR in the final rule at FAR 19.703(a)(2), 52.219–8(d), 52.219–9(c)(2), and Alternate IV of 52.219–9 at paragraph (c)(2), to clarify that a prime contractor acting "in good faith" is not held liable for misrepresentations made by the subcontractor regarding its size or socioeconomic status. SBA regulations at 13 CFR 121.411(b), provide that prime contractors may accept a subcontractor's electronic self-certification as to its size, if the subcontract contains a clause that provides that the subcontractor verifies by its submission of the offer that the size or socioeconomic representations and certifications made in the SAM (or any successor representations system) are current, accurate, and complete as of the date of the offer for the subcontract. SBA's regulations at 13 CFR 121.411(h), 124.1015(d), 125.29(d), 126.900(d), and 127.700(d) afford the "safe harbor" protection to the prime contractor for the subcontractor's misrepresentation of its size or socioeconomic status representation or certification. SBA's regulations serve as the regulatory basis for this FAR rule.

6. Orders

a. Goals

Comment: A number of respondents commented on the rule explicitly authorizing contracting officers to establish small business subcontracting goals for orders. One respondent submitted a number of questions seeking clarification on this authority, which indicated that the respondents believed the authority was tantamount to requiring a subcontracting plan for an order. The other respondent assumed that the authority to establish goals for orders was separate from a requirement for a subcontracting plan for orders and suggested language for the rule that would make this clear. This respondent also commented that unless the goals established on orders were higher than the goals established on the parent contract, the prime contractor may not meet its goals under the parent contract.

Response: The final rule has been revised at FAR 19.705–1 and 19.705–2 to clarify that contracting officers may only establish subcontracting goals at the order level, not subcontracting plans. The authority remains discretionary for ordering contracting officers, *i.e.,* the contracting officer may choose to establish goals for any order or not. The rule also maintains the discretion of the contracting officer to establish whatever goal they deem appropriate for an order.

b. Reporting Requirements

Comment: Two respondents submitted comments and questions relating to the requirement that prime contractors provide subcontracting data for each order when reporting subcontracting achievements for multiple-award contracts intended for use by multiple agencies.

One respondent commented that due to the volume of orders, a contractor may not be able to comply with this requirement and that the benefits of this requirement are minimal, but may result in driving up contract cost. The respondent suggested that the order-level reporting be an optional requirement, as opposed to a mandatory one, and also recommended that the requirement only apply when goals are established on orders.

Response: This rule is implementing regulatory changes made by SBA, which include the mandatory order-level reporting requirement. In addition to compliance with SBA's regulations, the order-level reporting requirement has the benefit of facilitating the allocation of subcontracting credit to funding agencies; proper allocation of credit ensures that funding agencies are incentivized to promote small business subcontracting on orders. The Councils are working with the Integrated Award Environment (IAE) to ensure that eSRS facilitates order-level reporting in a way that minimizes the additional burden to contractors.

Comment: Both respondents asked whether this reporting requirement would apply to existing multiple-award contracts or only to those contracts awarded after the rule becomes final.

Response: The order-level reporting requirement will apply via the updated FAR clause 52.219–9, Small Business Subcontracting Plan. Unless otherwise specified, FAR changes are applied to solicitations and contracts in accordance with FAR 1.108(d).

Comment: One of the respondents asked whether this reporting requirement would apply to all orders or only orders of a certain dollar value and whether this requirement is optional for single-award, indefinite delivery, indefinite quantity contracts.

Response: As the rule states at FAR 19.704(a)(10)(iii) and 52.219–9(d)(10)(iii), subcontracting data is required for each order, regardless of dollar value. The rule has been revised to now also require order-level reporting on single-award indefinite delivery, indefinite quantity contracts intended for use by multiple agencies in order to ensure that subcontracting credit is allocated based on funding agencies for all contracts, not just multiple-award contracts in use by multiple agencies.

7. Failure To Make a Good Faith Effort

Comment: One respondent pointed out that depending on how "good faith effort" is defined, the rule could be tantamount to requiring a "guaranteed work share."

Response: The FAR does not provide a definition for the phrase "good faith effort." However, "failure to make a good faith effort to comply with the subcontracting plan" is defined in paragraph (a) of the clause at FAR 52.219–16, Liquidated Damages—Subcontracting Plan, which is further explained at FAR 19.705–7(d); the SBA gives further guidance at 13 CFR 125.3. Also, neither SBA's regulations nor the FAR rule establish a requirement for a "guaranteed work share."

Comment: One respondent objected to characterizing the failure to comply in good faith with the subcontracting plan as a material breach of contract, since material breaches are typically tied to key objectives or contract targets. Therefore, using the "good faith" standard would be an inappropriate and punitive basis for something as drastic as contract termination.

Response: Fulfillment of the small business subcontracting plan is not merely ancillary to the objective of a contract. Failure of a contractor to comply in good faith with its subcontracting plan is a failure to perform an obligation on which the award of the contract was predicated.

The principle that a failure to comply in good faith with the subcontracting plan is a material breach of contract predates this FAR rule. The typical remedy provided in the FAR when the contracting officer decides that the contractor failed to comply in good faith with its subcontracting plan is the assessment of liquidated damages in accordance with FAR clause 52.219–16. However, neither this remedy nor any other remedy the contracting officer decides is appropriate can be characterized as punitive. Rather, liquidated damages are imposed so as to compensate the Government for the contractor's failure to fulfill a material obligation of the contract.

Comment: Three respondents agreed that failure to fulfill subcontracting goals is a material breach of contract. However, one respondent was unclear as to the process the contractor needs to follow should the contracting officer advise that the contractor has failed to make a good faith effort. One other respondent stated that stricter penalties for negative behavior should be employed.

Response: The procedures the contractor will follow should it receive written notification from the contracting officer of its failure to make a good faith effort are provided at FAR clause 52.219–16. In terms of amending the FAR to provide for stricter penalties, the Councils do not have statutory authority to do so.

8. Flow Down of Subcontracting Plan Requirements to Subcontractors

A few respondents submitted comments related to paragraph (j) of FAR clause 52.219–9, which provides guidance on the flow down of the clause to subcontractors.

Comment: One respondent suggested clarification to FAR clause 52.219–9(j) to emphasize that subcontracting plans are not required from subcontractors when the prime contract contains the clause at FAR 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items. The respondent suggests the clarification because of their experience with agencies' interpreting the FAR as requiring prime contractors with commercial plans to flow down the subcontracting plan requirement if the subcontractor is not providing a commercial item.

Response: The changes suggested to paragraph (j) of FAR clause 52.219–9 are not in keeping with the statutory requirements or SBA's implementing regulations.

Comment: The other respondents suggested clarification of the proposed text at FAR 52.219–9(l) in order to avoid misinterpretation of the new language, which would put it in direct conflict with paragraph (j) of FAR clause 52.219–9. Specifically, the respondents stated that the revised language "subcontract awards by affiliates shall be treated as subcontract awards by the Contractor" will be interpreted as requiring subcontracting plans from subcontractors providing commercial items through flow down of FAR clause 52.219–9.

Response: There is no reason to interpret the proposed language as requiring flow down of the clause to subcontractors. Paragraph (l) of FAR clause 52.219–9 addresses the reporting requirements and what a contractor may or may not take credit for when reporting its subcontracting achievements. The existing language in paragraph (l) states that a contractor cannot take credit for (*i.e.,* report as subcontracting) purchases from an affiliate. The new language, in keeping with SBA's final rule, clarifies that subcontract awards made by affiliates shall be treated as subcontract awards made by the contractor. Therefore, the contractor must take credit for first-tier subcontracts entered into by an affiliate.

9. Notification to Unsuccessful Offerors for Subcontracts

Comment: Three respondents commented on the proposed rule clarifying that prime contractors notify unsuccessful offerors for subcontracts in writing.

One respondent indicated that the requirement should also include a detailed explanation from the prime why the subcontractor was unsuccessful, as well as the granting of a cure period. Another remarked that due to the high volume of procurements, it is not always possible or realistic to notify unsuccessful offerors in writing, regardless of size. The onus should be on the supplier to follow up on the status of award and whether the subcontractor has been selected. The third respondent recommends that primes must offer these unsuccessful subcontractors an in-person or oral debriefing (subcontractor's choice) and offer at least five business days from the notification date to request that debriefing.

Response: The requirement for prime contractors to notify unsuccessful small business offerors parallels SBA's regulations at 13 CFR 125.3(c)(1)(viii), which contemplate a pre-award written notification as to the name and location of the apparent successful offeror and whether the successful offeror is a small business and if so, its socioeconomic categories. The Councils note that FAR clause 52.219–9 already included the requirement for notification; this rule is only adding the requirement that the notification include the socioeconomic status of the successful subcontract offeror and clarifying that the notification occur before award of the subcontract. It is not within the scope of this FAR Case to levy an additional period on prime contractors.

10. Contractors' Written Explanation for Not Using Small Business Subcontractors

A number of respondents commented on the rule requiring a prime contractor's written explanation as to why it did not utilize small business concerns to the same extent that the small business was used in preparing the bid or proposal.

Comment: One respondent recommended the explanation or report should be available to the subcontractor for review after submission and the small business be afforded the opportunity to add any relevant facts.

Response: SBA's regulations at 13 CFR 125.3(c)(4) only provide that the written explanation be provided to the contracting officer prior to the submission of the invoice for final payment and contract close-out. The SBA final rule did not contemplate an adjudicative process for small businesses to provide additional input. Therefore, it is not within the scope of this FAR Case to address this issue.

Comment: One respondent commented that section 1322 of the Small Business Jobs Act, implemented in proposed FAR 19.704(a)(12) and (13), will decrease opportunity for small business because it will drive prime contractors away from identifying potential small businesses in their subcontracting plans. Primes are encouraged to list no small businesses or large businesses to avoid punishment should a potential small business not be utilized based on unforeseen circumstances between proposal and subcontract award.

Response: The intent of incorporating SBA's revised regulations at 13 CFR 125.3(c)(4) into the FAR is to increase the likelihood that the contractor will carefully consider its small business supplier base when developing the small business subcontracting plan, and in doing so will more likely be capable of adhering to the assurances it made in the plan. FAR 19.702 already requires that any contractor receiving a contract for more than the simplified acquisition threshold must agree in the contract that small business concerns will have the maximum practicable opportunity to participate in contract performance.

Comment: One respondent commented that FAR 19.704(a)(13) is left to the offending contractor and is considered timely if "submitted to the contracting officer within 30 days of contract completion." Such timing makes the anticipated statutory relief illusory. The respondent suggests amending FAR 19.704(a)(13) (and corresponding modifications to FAR clause 52.219–9) to require the contractor to provide the written notice within 5 days of making a decision not to utilize a subcontractor or supplier described in FAR 19.704(a)(12), as well as written explanation supporting the alternative decision.

Response: The FAR rule is predicated on SBA's regulation at 13 CFR 125.3(c)(4), which provides that the written explanation must be submitted to the contracting officer prior to the submission of the invoice for final payment and contract close-out. However, the FAR rule provides a shorter timeframe (*i.e.,* within 30 days of contract completion) than SBA's regulations provide in order to comply with a related requirement in SBA's regulations (see 13 CFR 125.3(d)(4)) that contracting officers use the written explanation in the performance assessment for the prime contractor. The SBA final rule did not contemplate an additional notice period and, therefore, it is not within the scope of this FAR rule.

Comment: One respondent recommended that prime contractors that do not utilize small business in their subcontracting plans have points deducted when other offerors include small businesses in their subcontracting plans.

Response: SBA's regulations at 13 CFR 125.3 do not contemplate such a requirement. However, there is nothing in the FAR that precludes the contracting officer from including evaluation criteria in the solicitation that will allow the contracting officer to evaluate the extent to which offerors identify and commit to small business participation in the contract.

11. Privity

Comment: One respondent stated that permitting a subcontractor to discuss payment or utilization matters with the contracting officer will allow the subcontractor to establish its own relationship with the contracting officer. Another respondent recommended that the FAR be amended to require that contracting officers monitor contractors' compliance in terms of not prohibiting subcontractors from discussing matters of payment or non-utilization with the contracting officer. A third recommended that where a subcontractor has furnished an allegation of lack of good faith effort to the contracting officer, the contracting officer must share the submission with the contractor to make them aware of the allegation.

Response: The recommendations made by these respondents are not in keeping with the principles of privity.

Although limited communication between the contracting officer and the subcontractor may occur in accordance with this clause, it is not the role of the contracting officer to take any action on behalf of the subcontractor; rather, any action the contracting officer may take will be with respect to the contractor. As SBA noted in its final rule, the contracting officer cannot be a party to disputes between the contractor and its subcontractor, although he or she will be involved in evaluating the contractor's subcontracting performance. FAR Case 2014–004, Payment of Subcontractors, provides more specific guidance related to payments to subcontractors.

12. Use of the Term "Contractor" Versus "Prime Contractor"

Comment: Two respondents found that the use of the terms "Contractor" and "prime Contractor" in FAR clause 52.219–9 was somewhat confusing, since it was not clear when a requirement applied to the prime contractor alone, or to the prime and a subcontractor at a first or lower tier. These respondents recommended that the term "prime Contractor" be used for those requirements that apply only to prime contractors.

Response: This recommendation was not adopted by the Councils. The clause is intended to reflect the relationship between the prime contractor and the Federal agency that executed the contract; therefore, the terms "Contractor" and "prime Contractor" as used in the clause, are synonymous and mean the "prime contractor." Within the context of the prime contract, requirements that must be fulfilled by subcontractors will be indicated by use of the term "subcontractor."

13. Prime Contractor—Subcontractor Relationship

Comment: One respondent commented that the liability of a prime contractor to the small business subcontractor for not complying with its subcontracting plan should be unlimited, to include the loss of revenue, loss of profits, and loss of goodwill, which will likely be irreparable, and also indicated the rule would have implications to exclusivity provisions in teaming arrangements and/or subcontracts.

Response: Neither SBA's final rule nor the FAR prescribe elements to be considered in determining the liability of a prime contractor to its subcontractor when the prime contractor has not acted in "good faith." Further, the FAR does not prescribe "exclusivity provisions" in either teaming agreements or subcontracts; therefore, the rule cannot address implications to these relationships.

14. Funding Agencies Receiving Subcontracting Credit

Comment: One respondent stated their support of the initiative to allocate subcontracting credit based on funding agency and explained that this change, being applied to all contracts, will provide consistent methodology and reliable data, and will prohibit funding agencies from picking and choosing types of contracts based on whether or not they could get subcontracting credit.

Response: The Councils acknowledge receipt of the comment.

Comment: One respondent commented that they are uncertain of the impact of the rule in changing the way subcontracting credit is allocated across Government, *i.e.,* from contracting agency to funding agency, considering the rule ties the new order-level reporting requirement to only those multiple-award contracts with individual subcontracting plans, that require Individual Subcontract Reports (ISRs). The respondent stated that many Governmentwide acquisition contracts (GWACs) and Federal Supply Schedule (FSS) contracts have commercial plans for which there are only Summary Subcontract Reports (SSRs), not ISRs, and the SSRs are how agencies are allocated subcontracting credit.

Response: In addition to the requirement for order-level reporting on contracts like GWACs and FSS with individual subcontracting plans (*i.e.,* contracts that require ISRs), the proposed rule contained minute changes to the requirement for SSRs, which would facilitate funding agencies getting credit for all other contracts.

15. Systems-Related Concerns

Two respondents submitted comments and questions related to implementation of the rule's requirements in Governmentwide systems such as Federal Procurement Data System (FPDS) and eSRS.

Comment: Two respondents pointed out that FPDS and eSRS would need to be modified to allow for order-level reporting of subcontracting achievements. One respondent also pointed out that FPDS and eSRS would need to be modified to allow for funding agencies to receive subcontracting credit for all contracts.

Response: The Councils are aware that eSRS does not currently allow for order-level reporting and are working with IAE to ensure this capability is implemented in eSRS. The rule has been revised to clarify that the order-level reporting requirement applies after November 30, 2017, which is when eSRS is expected to accommodate the requirement. The Councils are also working with IAE to facilitate reporting of SSRs based on funding agency so as to ensure the appropriate agency gets subcontracting credit but contractors can continue to report SSRs as they do now and still be compliant with the revised FAR clause 52.219–9.

Comment: One respondent asked whether eSRS would be modified to capture NAICS codes on Individual Subcontracting Reports (ISRs).

Response: No changes will be made to eSRS to capture NAICS codes on reports. The rule has been revised to remove the requirement for contractors to list NAICS codes in the subcontracting plan.

Comment: One respondent asked whether FPDS and eSRS would be modified to accommodate the scenarios where a contracting officer established subcontracting goals in terms of total contract dollars.

Response: There will be no need for changes to FPDS or eSRS to accommodate those contracts with individual subcontracting plans where a contracting officer established subcontracting goals in terms of total contract dollars. eSRS already provides for an ability to report subcontracting achievements in terms of total contract dollars in ISRs, by using the "Base and All Options Value" field from FPDS as a basis for the calculations. The rule provides for a definition of "total contract dollars" so when contracting officers complete the "Base and All Options Value" field in FPDS accordingly, the business rules are already in place in FPDS and eSRS to accommodate those subcontracting plans for which goals in terms of total contract dollars have been established.

16. Lack of Burden Analysis

Comment: One respondent recommended that the FAR rule clearly exempt commercial or commercially available off-the-shelf (COTS) item suppliers from the revisions at FAR clause 52.219–9, since the Small Business Jobs Act of 2010 made no mention of applying the changes set forth in the rule to commercial items or COTS items. The alternative suggestion from this respondent was for the FAR Council to address the omission of the burden analysis and/or produce some evidence to support the claim that applying the proposed rule to commercial/COTS suppliers is in the best interests of the Federal Government.

Response: The Councils did not adopt this respondent's recommendation, because neither the law nor SBA's regulations provide an exemption for the application of the requirements in this rule to acquisitions for commercial or COTS items (although in the case of a contract for commercial or COTS items, the contractor is not required to flow down the subcontracting FAR clause at 52.219–9 to subcontractors). The use of a commercial subcontracting plan is preferred for contractors furnishing commercial items, since many of the requirements associated with small business subcontracting plans are either streamlined or are not applicable to commercial plans. Nevertheless, a contractor that has been awarded a contract that meets the statutory requirements for a subcontracting plan must comply with the requirements discussed in this rule. Historically, FAR clause 52.219–9 has been applied to acquisitions for commercial and COTS items, as demonstrated by FAR clause 52.212–5(b).

An analysis of the public burden associated with the implementation of this rule, pursuant to the Paperwork Reduction Act, as amended (44 U.S.C. chapter 35) and an analysis of the impact of the rule on small entities in accordance with the Regulatory Flexibility Act was provided in sections V and VI of the preamble to the proposed rule. Pursuant to 41 U.S.C. 1906, the requirements of this rule will apply to the acquisitions of commercial items because the FAR Council made a written determination that it would not be in the best interest of the Federal Government to exempt acquisitions of commercial items. Pursuant to 41 U.S.C. 1907, the requirements of this rule will apply to the acquisitions of COTS items because the Administrator of Federal Procurement Policy made a written determination that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items. A summary of the determinations, the final Paperwork Reduction Act and Regulatory Flexibility Act analyses will be provided in sections III, V, and VI of the preamble to the final rule.

17. Out of Scope

a. Credit for Subcontracts Awarded to AbilityOne

Comment: One respondent inquired as to whether eSRS would be modified to allow contractors to receive credit for making subcontract awards to AbilityOne. The respondent also inquired if this would become more important than meeting the small business subcontracting goals.

Response: This inquiry relates to matters that are beyond the scope of the rule. Prime contractors may only take credit for subcontract awards made to AbilityOne participating non-profit agencies when the awarding agency has specific statutory authority to do so. Otherwise, subcontracting credit can only be taken for subcontracts made to small business concerns, which by definition are for-profit entities.

b. Matters Related to the HUBZone Program

Comment: One respondent requested several changes to SBA's HUBZone program eligibility requirements.

Response: In the FAR rule, only the definitions for "HUBZone contract" and "HUBZone small business concern" were amended, so as to clarify that the representation of HUBZone status cannot be done through "self-certification." Changes to the eligibility requirements for HUBZone small business concerns can only be made by SBA, which has the statutory authority to administer the HUBZone program. Accordingly, the respondent's recommended changes are beyond the scope of the FAR rule.

c. Inclusion of Insurance Costs in the Subcontracting Base

Comment: Many respondents expressed concern regarding the requirement that prime contractors must exclude insurance costs from the subcontracting base, and claimed that this would be a disincentive for prime contractors to award subcontracts to small businesses in this industry sector. These respondents requested that insurance costs be included in the subcontracting base.

Response: The SBA regulation at 13 CFR 125.3(a)(1)(iii) lists items that should not be included in the subcontracting base. One item is employee insurance. The FAR does not address the subject. Questions concerning whether or not certain insurance expenses should be excluded from the subcontracting base are beyond the scope of this rule and must be directed to SBA.

d. Unilateral Termination of a Subcontract

Comment: One respondent stated that there should be a separate proposed rule prescribing that a prime contractor cannot prevent a subcontractor from unilaterally terminating a subcontract or teaming agreement in the event the subcontractor does not receive its adequate work share.

Response: This comment is beyond the scope of this rule, since it addresses the specific relationship between the prime and its subcontractor.

e. Small Business Participation Plan

Comment: One respondent commented on the scenario where a subcontracting plan would be required once a small business contractor rerepresents as other than small business. This respondent expressed concern that in such a scenario, the contractor would no longer be able to comply with the small business utilization commitments made in its "Small Business Participation Plan," which in turn would reflect negatively on its contact performance.

Response: The proposed rule does not address "Small Business Participation Plans;" rather, the rule addresses the discretionary authority of the contracting officer to require a subcontracting plan should the small business represent a change of size status from small to other than small. Furthermore, although some contracting officers have requested prime contractors to provide a "Small Business Participation Plan," it is not a policy prescribed in the FAR and therefore addressing the administrative procedures associated with this technique is beyond the scope of the rule.

f. Definitions

Comment: One respondent provided revisions to the definition of "small business subcontractor" in FAR 2.101 and to the definition of "master subcontracting plan" in FAR 19.701 and recommended they be incorporated into the FAR rule.

Response: The revisions proposed to the definitions are beyond the scope of this rule, as they are not based on changes or clarifications that SBA has made in their final rule.

18. Miscellaneous Edits and Clarifications

Comment: Two respondents pointed out typos in the proposed rule, specifically at FAR clause 52.219–9(d)(1) and 52.219–9(d)(6).

Response: The rule has been revised at FAR clauses 52.219–9(d)(1) and 52.219–9(d)(6) to correct the typos.

Comment: One respondent suggested edits to the language regarding master subcontracting plans in paragraphs (b) and (f)(1) of FAR clause 52.219–9. The respondent's suggestion was to specify that master subcontracting plans are to be "approved by the Administrative Contracting Office."

Response: The Councils did not adopt the suggested edits. The statutory requirements and SBA's revised regulations being implemented in this rule do not require that a master subcontracting plan be approved by the "Administrative Contracting Office."

C. Other Changes

This final rule contains the following additional changes:

- A reference to 19.705–2(b)(3) has been added to 19.301–2(e) as a reminder of factors to consider when deciding whether to require a subcontracting plan under 19.301–2(e).
- The term "socioeconomic" has been added throughout the rule to differentiate between size status and socioeconomic status.
- Updates the text at 19.702(a)(3) and throughout the rule to reflect the October 1, 2015, inflationary adjustment to the subcontracting plan threshold.
- A technical edit at FAR 19.703(d)(2) to clarify that protests challenging the socioeconomic status of a HUBZone small business must be filed in accordance with 13 CFR 126.801.
- The introductory text of paragraph 19.704(a) has been revised to remove "required" so as to not imply that 19.301–2(e)(2) requires a subcontracting plan.
- The phrase "or any successor system" is removed from the rule since the FAR would be amended to reflect any successor to a system currently named in the FAR.
- Conforming changes are made to the cross-references at 19.704(c) and 52.219–9(l)(1)(ii)(B).
- Conforming changes are made to additional FAR clauses that reference FAR clause 52.219–8, *i.e.,* 52.212–5 basic and Alternate II, 52.213–4, and 52.244–6.
- Restores paragraph (E) of clause 52.219–9(l)(2)(i), which was mistakenly left out in the published proposed rule.
- Language has been added to 52.219–9 Alternate IV (c)(1) to make the same clarifications made in 19.705–2(e) regarding whether the goals in a subcontracting plan added post-award apply retroactively.
- Minor grammatical edits throughout the rule.

The final rule will not be making a change to the FAR 19.703(b) reference at FAR 19.305(c) as this is the appropriate reference for subcontractor size protests.

III. Applicability to Commercial Items, Including Commercially Available Off-the-Shelf Items

The Federal Acquisition Regulatory (FAR) Council has made the following determinations with respect to the rule's application of Section 1321 and 1322 of the Small Business Jobs Act of 2010, to contracts for the acquisition of commercial items and contracts for the acquisition of commercially available off-the-shelf (COTS) items.

A. Applicability to Contracts for the Acquisition of Commercial Items

Pursuant to 41 U.S.C. 1906, acquisitions of commercial items (other than acquisitions of COTS items, which are addressed in 41 U.S.C. 1907) are exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1906 and states that the law applies to acquisitions of commercial items; or (iii) the FAR Council makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of commercial items from the provision of law. If none of these conditions are met, the FAR is required to include the statutory requirement(s) on a list of provisions of law that are inapplicable to acquisitions of commercial items.

The purpose of this rule is to implement sections 1321 and 1322 of the Small Business Jobs Act of 2010.

Section 1321 requires promulgation of regulations on subcontracting compliance relating to small business concerns, including assignment of compliance responsibilities between contracting offices, small business offices, and program offices and periodic oversight and review activities.

Section 1322 amends the Small Business Act at 15 U.S.C. 637(d), to require a Federal contractor to make a good faith effort to utilize a small business subcontractor during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. If a prime contractor does not utilize a small business subcontractor as described above, the prime contractor is required to explain, in writing, to the contracting officer the reasons why it is unable to do so.

These statutory requirements are reflected in the Small Business Administration's (SBA's) final rule published at 78 FR 42391 on July 16, 2013, which did not exempt acquisitions of commercial items.

The law is silent on the applicability of these requirements to acquisitions of commercial items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1906 and its application to acquisitions of commercial items. Therefore, it does not apply to acquisitions of commercial items unless the FAR Council makes a written determination as provided in 41 U.S.C. 1906.

The law furthers the Administration's goal of supporting small business and advances the interests of small business subcontractors by encouraging prime contractors to comply with their stated subcontracting objectives. Increased compliance with subcontracting objectives will expand opportunities for small business subcontractors. Exclusion of a large segment of Federal contracting, such as acquisitions for commercial items, will limit the full implementation of these subcontracting-related objectives. Further, the primary FAR clauses implementing Federal procurement policies governing subcontracting with small business, 52.219–8, Utilization of Small Business Concerns and 52.219–9, Small Business Subcontracting Plan, are currently prescribed for use in solicitations for commercial items. This rule merely revises FAR clause 52.219–9 to implement the new requirements of sections 1321 and 1322. Exclusion of acquisitions for commercial items from these requirements would create confusion among contractors and the Federal contracting workforce. The burden on contractors would not increase significantly if the new requirements of sections 1321 and 1322 were applied to acquisitions for commercial items. Under the FAR clauses noted above, contractors are already required to commit to objectives for subcontracting with small business concerns under contracts for commercial items above the subcontracting plan threshold. The effort required for contractors to comply with the new requirements will be relatively small.

For these reasons, it is in the best interest of the Federal Government to apply the subcontracting requirements to all contracts above the subcontracting plan threshold.

B. Applicability of Contracts for the Acquisition of COTS Items

Pursuant to 41 U.S.C. 1907, acquisitions of COTS items will be exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1907 and states that the law applies to acquisitions of COTS items; (iii) concerns authorities or responsibilities under the Small Business Act (15 U.S.C. 644) or bid protest procedures developed under the authority of 31 U.S.C. 3551 *et seq.,* 10 U.S.C. 2305(e) and (f), or 41 U.S.C. 3706 and 3707; or (iv) the Administrator for Federal Procurement Policy makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items from the provision of law. If none of these conditions are met, the FAR is required to include the statutory requirement(s) on a list of provisions of law that are inapplicable to acquisitions of COTS items.

The purpose of this rule is to implement sections 1321 and 1322 of the Small Business Jobs Act of 2010.

Section 1321 requires promulgation of regulations on subcontracting compliance relating to small business concerns, including assignment of compliance responsibilities between contracting offices, small business offices, and program offices and periodic oversight and review activities.

Section 1322 amends the Small Business Act at 15 U.S.C. 637(d), to require a Federal contractor to make a good faith effort to utilize a small business subcontractor during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. If a prime contractor does not utilize a small business subcontractor as described above, the prime contractor is required to explain, in writing, to the contracting officer the reasons why it is unable to do so.

These statutory requirements are reflected in the SBA's final rule published at 78 FR 42391 on July 16, 2013, which did not exempt acquisitions of COTS items.

The law is silent on the applicability of these requirements to acquisitions of COTS items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1907 and its application to acquisitions of COTS items. Therefore, it does not apply to acquisitions of COTS items unless the Administrator for Federal Procurement Policy makes a written determination as provided in 41 U.S.C. 1907.

The law furthers the Administration's goal of supporting small business and advances the interests of small business subcontractors by encouraging prime contractors to comply with their stated subcontracting objectives. Increased compliance with subcontracting objectives will expand opportunities for small business subcontractors. Exclusion of a large segment of Federal contracting, such as acquisitions for COTS items, will limit the full implementation of these subcontracting-related objectives. Further, the primary FAR clauses implementing Federal procurement policies governing subcontracting with small business, 52.219–8, Utilization of Small Business Concerns and 52.219–9, Small Business Subcontracting Plan, are currently prescribed for use in solicitations for COTS items. This rule merely revises FAR clause 52.219–9 to implement the new requirements of sections 1321 and 1322. Exclusion of acquisitions for commercial items from these requirements would create confusion among contractors and the Federal contracting workforce. The burden on contractors would not increase significantly if the new requirements of sections 1321 and 1322 were applied to acquisitions for commercial items. Under the FAR clauses noted above, contractors are already required to commit to objectives for subcontracting with small business concerns under contracts for commercial items above the subcontracting plan threshold. The effort required for contractors to comply with the new requirements will be relatively small.

For these reasons, it is in the best interest of the Federal Government to apply the subcontracting requirements to all contracts above the subcontracting plan threshold.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

> This final rule amends the FAR to provide uniform guidance on small business subcontracting consistent with the Small Business Administration's (SBA's) final rule published at 78 FR 42391, on July 16, 2013, which implements sections 1321 and 1322 of the Small Business Jobs Act of 2010 (Public Law 111–240). SBA's final rule also implements other changes intended to help small business subcontractors by requiring other than small prime contractors to report data on small business subcontracting in connection with orders.
>
> The objectives of this rule are to implement statutory requirements, as well as make improvements to increase subcontracting opportunities for small businesses.
>
> This rule may have a positive economic impact on any small business entity that wishes to participate in the Federal procurement arena as a subcontractor. Analysis of the System for Award Management (SAM) database indicates there are over 307,846 small business registrants. It is unknown how many of these concerns participate in small business subcontracting. Firms do not need to register in the SAM database to participate in subcontracting. Thus, the number of firms participating in subcontracting may be greater than or lower than the number of firms registered in the SAM database.
>
> There were no significant issues raised by the public in response to the Initial Regulatory Flexibility Analysis provided in the proposed rule.
>
> This rule does not impose any new reporting, recordkeeping or other compliance requirements for small businesses.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of SBA.

VI. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies. The rule contains information collection requirements. OMB has cleared these information collection requirements under OMB Control Number 9000–0192, titled: Utilization of Small Business Subcontractors, in the amount of 5,328 burden hours; OMB Control Number 9000–0006, titled: Subcontracting Plans/Subcontract Report For Individual Contracts, in the amount of 2,403,108 burden hours; and OMB Control Number 9000–0007, titled: Subcontracting Plans/Summary Subcontract Report, in the amount of 534,024 burden hours. No comments were received on the information collection requirements so no revisions were made to the collections. The burden hours for 9000–0006 and 9000–0007 include both existing information collection requirements associated with subcontracting plans, as well as the new information collection requirements in this rule.

List of Subjects in 48 CFR Parts 1, 2, 15, 19, and 52

Government procurement.

Dated: June 30, 2016.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA are amending 48 CFR parts 1, 2, 15, 19, and 52, as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 2, 15, 19, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.106 [Amended]

■ 2. Amend section 1.106 by removing from the table, FAR segments "19.7" and "52.219–9" and their corresponding OMB control numbers "9000–0006 and 9000–0007" and adding, in numerical sequence, FAR segments "19.7" and "52.219–9" and their corresponding OMB control numbers "9000–0192, 9000–0006, and 9000–0007" in their places.

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 3. Amend section 2.101 in paragraph (b)(2) by revising the introductory text of the definition "HUBZone contract" and the definitions "HUBZone small business concern" and "Small business subcontractor" to read as follows:

2.101 Definitions.

* * * * *

HUBZone contract means a contract awarded to a Small Business Administration certified "HUBZone small business concern" through any of the following procurement methods:

* * * * *

HUBZone small business concern means a small business concern, certified by the Small Business Administration (SBA), that appears on the List of Qualified HUBZone Small Business Concerns maintained by the SBA (13 CFR 126.103).

* * * * *

Small business subcontractor means a concern that does not exceed the size standard for the North American Industry Classification Systems code that the prime contractor determines best describes the product or service being acquired by the subcontract.

* * * * *

PART 15—CONTRACTING BY NEGOTIATION

■ 4. Amend section 15.304 by—

■ a. Revising paragraph (c)(3)(i); and

■ b. Removing from paragraphs (c)(3)(ii) and (c)(4) "must" and adding "shall" in their places.

The revision reads as follows:

15.304 Evaluation factors and significant subfactors.

* * * * *

(c) * * *

(3)(i) Past performance, except as set forth in paragraph (c)(3)(iii) of this section, shall be evaluated in all source selections for negotiated competitive acquisitions expected to exceed the simplified acquisition threshold.

* * * * *

PART 19—SMALL BUSINESS PROGRAMS

■ 5. Amend section 19.301–2 by revising paragraph (e) to read as follows:

19.301–2 Rerepresentation by a contractor that represented itself as a small business concern.

* * * * *

(e) A change in size status does not change the terms and conditions of the contract. However, the contracting officer may require a subcontracting plan for a contract containing 52.219–9, Small Business Subcontracting Plan, if a prime contractor's size status changes from small to other than small as a result of a size rerepresentation (see 19.705–2(b)(3)).

19.305 [Amended]

■ 6. Amend section 19.305 by removing from paragraph (c) "19.703(a)(2)" and adding "19.703(e)" in its place.

■ 7. Amend section 19.701 by—

■ a. Removing the definitions "Individual contract plan" and "Master plan"; and

■ b. Adding in alphabetical order definitions for "Individual subcontracting plan" and "Master subcontracting plan" and "Total contract dollars".

The additions read as follows:

19.701 Definitions.

* * * * *

Individual subcontracting plan means a subcontracting plan that covers the entire contract period (including option periods), applies to a specific contract, and has goals that are based on the offeror's planned subcontracting in support of the specific contract, except that indirect costs incurred for common or joint purposes may be allocated on a prorated basis to the contract.

Master subcontracting plan means a subcontracting plan that contains all the required elements of an individual subcontracting plan, except goals, and may be incorporated into individual subcontracting plans, provided the master subcontracting plan has been approved.

* * * * *

Total contract dollars means the final anticipated dollar value, including the dollar value of all options.

■ 8. Amend section 19.702 by—

■ a. Removing from the first sentence of the introductory text "for more" and adding "with a value greater" in its place;

■ b. Removing from paragraph (a) introductory text "Section" and adding "section" in its place;

■ c. Removing from paragraphs (a)(1) and (2) "a contract or contract modification, that individually is" and adding "a contract that is" in their places, respectively;

■ d. Adding paragraph (a)(3); and

■ e. Revising paragraph (b)(4).

The addition and revision read as follows:

19.702 Statutory requirements.

* * * * *

(a) * * *

(3) Each contract modification that causes the value of a contract without a subcontracting plan to exceed $700,000 ($1.5 million for construction), shall require the contractor to submit a subcontracting plan for the contract, if the contracting officer determines that subcontracting opportunities exist.

(b) * * *

(4) For modifications that are within the scope of the contract and the contract does not contain the clause at 52.219–8, Utilization of Small Business Concerns.

* * * * *

■ 9. Amend section 19.703 by—

■ a. Adding a sentence to the end of paragraph (a)(1);

■ b. Revising paragraphs (a)(2) and (b);

■ c. Removing from paragraph (d)(1) introductory text "System for Award Management" and adding "SAM" in its place;

■ d. Removing from paragraph (d)(1)(i) "or *http://www.sba.gov/hubzone*";

■ e. Removing from paragraph (d)(1)(ii) "HUB" and adding "HUBZone Program" in its place;

■ f. Revising paragraph (d)(2); and

■ g. Adding paragraph (e).

The additions and revisions read as follows:

19.703 Eligibility requirements for participating in the program.

* * * * *

(a) * * *

(1) * * * For subcontracting purposes, a concern is small if it does not exceed the size standard for the

NAICS code that the prime contractor determines best describes the product or service being acquired by the subcontract.

(2)(i) The prime contractor may accept a subcontractor's written representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business, if the subcontractor represents that the size and socioeconomic status representation with its offer are current, accurate, and complete as of the date of the offer for the subcontracts; or

(ii) The prime contractor may accept a subcontractor's representation of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business in the System for Award Management (SAM) if—

(A) The subcontractor is registered in SAM; and

(B) The subcontractor represents that the size and socioeconomic status representations made in SAM are current, accurate and complete as of the date of the offer for the subcontract.

(iii) The prime contractor may not require the use of SAM for the purposes of representing size or socioeconomic status in connection with a subcontract.

(iv) In accordance with 13 CFR 121.411, 124.1015, 125.29, 126.900, and 127.700, a prime contractor acting in good faith is not liable for misrepresentations made by its subcontractors regarding the subcontractor's size or socioeconomic status.

(b) The contractor, the contracting officer, or any other interested party can challenge a subcontractor's size status representation by filing a protest, in accordance with 13 CFR 121.1001 through 121.1008.

* * * * *

(d) * * *

(2) Protests challenging the socioeconomic status of a HUBZone small business concern must be filed in accordance with 13 CFR 126.801.

(e) The contracting officer or the SBA may protest the disadvantaged status of a proposed subcontractor. Protests challenging a subcontractor's small disadvantaged business representation must be filed in accordance with 13 CFR 124.1007 through 124.1014. Other interested parties may submit information to the contracting officer or the SBA in an effort to persuade the contracting officer or the SBA to initiate a protest. Such protests, in order to be considered timely, must be submitted to the SBA prior to completion of performance by the intended subcontractor.

■ 10. Amend section 19.704 by—

■ a. Revising paragraph (a) introductory text and paragraphs (a)(2) and (3);

■ b. Redesignating paragraphs (a)(10)(iii) through (vi) as paragraphs (a)(10)(iv) through (vii), respectively;

■ c. Adding new paragraph (a)(10)(iii);

■ d. Removing the semicolon from the end of newly designated paragraph (a)(10)(iv) introductory text and adding a period in its place;

■ e. Adding a sentence to the end of the newly designated paragraph (a)(10)(iv)(A);

■ f. Revising the newly designated paragraph (a)(10)(iv)(B);

■ g. Removing the periods from the ends of newly designated paragraph (a)(10)(vii) and (a)(11) and adding a semicolon in their places, respectively; and

■ h. Adding paragraphs (a)(12) through (14);

■ i. Removing from paragraph (b) "master" and adding "master subcontracting" in its place, three times, and removing "Master" and adding "Master subcontracting" in its place, once; and

■ j. Revising paragraph (c).

The revisions and additions read as follows:

19.704 Subcontracting plan requirements.

(a) Each subcontracting plan under 19.301–2(e) and 19.702(a)(1), (2), and (3) shall include—

* * * * *

(2) A statement of the total dollars planned to be subcontracted and a statement of the total dollars planned to be subcontracted to small business (including ANCs and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business (including ANCs and Indian tribes) and women-owned small business concerns, as a percentage of total subcontract dollars. For individual subcontracting plans only, a contracting officer may require the goals referenced in paragraph (a)(1) of this section to be calculated as a percentage of total contract dollars, in addition to the goals established as a percentage of total subcontract dollars;

(3) A description of the principal types of supplies and services to be subcontracted and an identification of types of supplies or services planned for subcontracting to small business (including ANCs and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business (including ANCs and Indian tribes), and women-owned small business concerns;

* * * * *

(10) * * *

(iii) After November 30, 2017, include subcontracting data for each order when reporting subcontracting achievements for indefinite-delivery, indefinite-quantity contracts intended for use by multiple agencies;

(iv) * * *

(A) * * * When a contracting officer rejects an ISR, the contractor is required to submit a revised ISR within 30 days of receiving the notice of the ISR rejection.

(B) The SSR shall be submitted annually by October 30 for the twelve-month period ending September 30. When an SSR is rejected, the contractor is required to submit a revised SSR within 30 days of receiving the notice of SSR rejection;

* * * * *

(12) Assurances that the offeror will make a good faith effort to acquire articles, equipment, supplies, services, or materials, or obtain the performance of construction work from the small business concerns that the offeror used in preparing the bid or proposal, in the same or greater scope, amount, and quality used in preparing and submitting the bid or proposal. Responding to a request for a quote does not constitute use in preparing a bid or proposal. An offeror used a small business concern in preparing the bid or proposal if—

(i) The offeror identifies the small business concern as a subcontractor in the bid or proposal or associated small business subcontracting plan, to furnish certain supplies or perform a portion of the contract; or

(ii) The offeror used the small business concern's pricing or cost information or technical expertise in preparing the bid or proposal, where there is written evidence of an intent or understanding that the small business concern will be awarded a subcontract for the related work if the offeror is awarded the contract;

(13) Assurances that the contractor will provide the contracting officer with a written explanation if the contractor fails to acquire articles, equipment, supplies, services or materials or obtain the performance of construction work as described in (a)(12) of this section. This written explanation will be submitted to the contracting officer within 30 days of contract completion; and

(14) Assurances that the contractor will not prohibit a subcontractor from discussing with the contracting officer any material matter pertaining to payment to or utilization of a subcontractor.

* * * * *

(c) For multiyear contracts or contracts containing options, the cumulative value of the basic contract and all options is considered in determining whether a subcontracting plan is necessary. If a subcontracting plan is necessary and the offeror is submitting an individual subcontracting plan, the individual subcontracting plan shall contain all the elements required by paragraph (a) of this section and shall contain separate statements and goals based on total subcontract dollars for the basic contract and for each option.

* * * * *

■ 11. Amend section 19.705–1 by—

■ a. Revising the section heading;

■ b. Redesignating the text as paragraph (a); and

■ c. Adding paragraph (b).

The revision and addition read as follows:

19.705–1 General.

* * * * *

(b)(1) Except where a contractor has a commercial plan, the contracting officer shall require a subcontracting plan for each indefinite-delivery, indefinite-quantity contract (including task or delivery order contracts, FSS, GWACs, and MACs), when the estimated value of the contract meets the subcontracting plan thresholds at 19.702(a)(1) and small business subcontracting opportunities exist.

(2) Contracting officers placing orders may establish small business subcontracting goals for each order. Establishing goals shall not be in the form of a new subcontracting plan as a contract may not have more than one plan (19.705–2(e)).

■ 12. Amend section 19.705–2 by—

■ a. Removing from the introductory text "must" and adding "shall" in its place;

■ b. Revising paragraph (a);

■ c. Adding paragraph (b)(3);

■ d. Revising paragraphs (c) and (e); and

■ e. Adding paragraph (f).

The revisions and additions read as follows:

19.705–2 Determining the need for a subcontracting plan.

* * * * *

(a)(1) Determine whether the proposed total contract-dollars will exceed the subcontracting plan threshold in 19.702(a).

(2) Determine whether a proposed modification will cause the total contract dollars to exceed the subcontracting plan threshold (see 19.702(a)).

(b) * * *

(3) Whether the firm can acquire any portion of the work with minimal or no disruption to performance (with consideration given to the time remaining until contract completion), and at fair market value, when a determination is made in accordance with paragraph (a)(2).

(c) If it is determined that there are no subcontracting possibilities, the determination-shall include a detailed rationale, be approved at a level above the contracting officer, and placed in the contract file.

* * * * *

(e) A contract may not have more than one subcontracting plan. However, a contracting officer may establish separate subcontracting goals for each order under an indefinite-delivery, indefinite-quantity contract (19.705–1(b)(2)). When a contract modification exceeds the subcontracting plan threshold (see 19.702(a)) or an option is exercised, the goals of an existing subcontracting plan shall be amended to reflect any new subcontracting opportunities not envisioned at the time of contract award. These goal changes do not apply retroactively.

(f) If a subcontracting plan has been added to the contract due to a modification (see 19.702(a)(3)) or a size re-representation (see 19.301–2(e)), the subcontracting goals apply from the date of incorporation of the subcontracting plan into the contract and the contractor's achievements must be reported on the ISR (or the SF–294, if applicable) on a cumulative basis from the date of incorporation of the subcontracting plan into the contract.

19.705–4 [Amended]

■ 13. Amend section 19.705–4 by removing from paragraph (b) "11 required" and adding "14 required" in its place; and removing from paragraph (c) "11 elements" and adding "14 elements" in its place.

■ 14. Amend section 19.705–6 by—

■ a. Revising the introductory text;

■ b. Removing from paragraph (a) "Notifying" and adding "Notify" in its place;

■ c. Removing from paragraph (b) "Forwarding" and adding "Forward" in its place;

■ d. Removing from paragraph (c) introductory text "Giving" and adding "Give" in its place;

■ e. Removing from paragraph (d) "Notifying" and adding "Notify" in its place;

■ f. Removing from paragraph (e) "Forwarding" and adding "Forward" in its place;

■ g. Redesignating paragraphs (f) through (h) as paragraphs (h) through (j), respectively;

■ h. Adding new paragraphs (f) and (g).

■ i. Removing from the newly designated paragraph (h) "Initiating" and adding "Initiate" in its place;

■ j. Removing from the newly designated paragraph (i) "Taking" and adding "Take" in its place; and

■ k. Removing from the newly designated paragraph (j) "Acknowledging" and "rejecting" and adding "Acknowledge" and "reject" in their places, respectively.

The revisions and additions read as follows:

19.705–6 Postaward responsibilities of the contracting officer.

After a contract or contract modification containing a subcontracting plan is awarded or an existing subcontracting plan is amended, the contracting officer shall do the following:

* * * * *

(f) Monitor the prime contractor's compliance with its subcontracting plan, to include the following:

(1) Ensure that subcontracting reports are submitted into the eSRS within 30 days after the report ending date (*e.g.,* by October 30th for the fiscal year ended September 30th).

(2) Review ISRs, and where applicable, SSRs, in eSRS within 60 days of the report ending date (*e.g.,* by November 30th for a report submitted for the fiscal year ended September 30th).

(3) Either acknowledge receipt of or reject the reports in accordance with subpart 19.7, 52.219–9, Small Business Subcontracting Plan, and the eSRS instructions (*www.esrs.gov*).

(i) The authority to acknowledge or reject SSRs for commercial plans resides with the contracting officer who approved the commercial plan.

(ii) If a report is rejected, the contracting officer must provide an explanation for the rejection to allow the prime contractor the opportunity to respond specifically to identified deficiencies.

(g) Evaluate the prime contractor's compliance with its subcontracting plan, to include the following:

(1) Assess whether the prime contractor made a good faith effort to comply with its small business subcontracting plan (see 13 CFR 125.3(d)(3)).

(2) Assess the prime contractor's written explanation concerning the prime contractor's failure to use a small business concern in the performance of the contract in the same scope, amount, and quality used in preparing and submitting the bid or proposal, if applicable.

* * * * *

■ 15. Amend section 19.708 by—

■ a. Removing the period at the end of paragraphs (b)(1)(i) and (ii) and adding a semicolon in their places;

■ b. Removing from paragraph (b)(1)(iii) "Alternate III." and adding "Alternate III; or" in its place;

■ c. Adding paragraph (b)(1)(iv);

■ d. Removing from paragraph (b)(2) "Alternate I, II, or III." and adding "Alternate I, II, III, or IV." in its place.

The addition reads as follows:

19.708 Contract clauses.

* * * * *

(b)(1) * * *

(iv) Incorporating a subcontracting plan due to a modification as provided for in 19.702(a)(3), the contracting officer shall use the clause with its Alternate IV.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 16. Amend section 52.212–5 by—

■ a. Revising the date of the clause;

■ b. Revising paragraphs (b)(16) and (17) and the first sentence of paragraph (e)(1)(ii); and

■ c. Amending Alternate II by revising the date of the alternate and the first sentence of paragraph (e)(1)(ii)(C).

The revisions read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (Nov 2016)

* * * * *

(b) * * *

__(16) 52.219–8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).

__(17)(i) 52.219–9, Small Business Subcontracting Plan (Nov 2016) (15 U.S.C. 637(d)(4)).

__(ii) Alternate I (Nov 2016) of 52.219–9.

__(iii) Alternate II (Nov 2016) of 52.219–9.

__(iv) Alternate III (Nov 2016) of 52.219–9.

__(v) Alternate IV (Nov 2016) of 52.219–9.

* * * * *

(e)(1) * * *

(ii) 52.219–8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. * * *

* * * * *

Alternate II (Nov 2016). * * *

(e)(1) * * *

(ii) * * *

(C) 52.219–8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. * * *

* * * * *

■ 17. Amend section 52.213–4 by revising the date of the clause and paragraph (a)(2)(viii) to read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (Nov 2016)

(a) * * *

(2) * * *

(viii) 52.244–6, Subcontracts for Commercial Items (Nov 2016).

* * * * *

■ 18. Amend section 52.219–8 by—

■ a. Revising the date of the clause;

■ b. Revising the definition in paragraph (a) of "HUBZone small business concern";

■ c. Revising paragraph (d)(1);

■ d. Redesignating paragraph (d)(2) as (d)(5); and

■ e. Adding new paragraphs (d)(2) through (4).

The revisions and additions read as follows:

52.219–8 Utilization of Small Business Concerns.

* * * * *

Utilization of Small Business Concerns (Nov 2016)

(a) * * *

HUBZone small business concern means a small business concern, certified by the Small Business Administration, that appears on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration.

* * * * *

(d)(1) The Contractor may accept a subcontractor's written representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business if the subcontractor represents that the size and socioeconomic status representations with its offer are current, accurate, and complete as of the date of the offer for the subcontract.

(2) The Contractor may accept a subcontractor's representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business in the System for Award Management (SAM) if—

(i) The subcontractor is registered in SAM; and

(ii) The subcontractor represents that the size and socioeconomic status representations made in SAM are current, accurate and complete as of the date of the offer for the subcontract.

(3) The Contractor may not require the use of SAM for the purposes of representing size or socioeconomic status in connection with a subcontract.

(4) In accordance with 13 CFR 121.411, 124.1015, 125.29, 126.900, and 127.700, a contractor acting in good faith is not liable for misrepresentations made by its subcontractors regarding the subcontractor's size or socioeconomic status.

* * * * *

■ 19. Amend section 52.219–9 by—

■ a. Revising the clause heading and the date of the clause;

■ b. In paragraph (b), removing the definitions "Individual contract plan" and "Master plan"; and adding, in alphabetical order, definitions for "Individual subcontracting plan" and "Master subcontracting plan" and "Total contract dollars".

■ c. Revising paragraph (c);

■ d. Revising paragraphs (d) introductory text, (d)(1) introductory text, paragraph (d)(1)(i), (d)(1)(ii) introductory text, (d)(2)(i), (d)(3) introductory text, (d)(5), (d)(6) introductory text, (d)(7) through (10), and (d)(11)(iv)(C);

■ e. Adding paragraphs (d)(12) through (14);

■ f. Revising paragraphs (e)(4) and (6);

■ g. Adding paragraph (e)(7);

■ h. Revising paragraphs (f), (i), (k), and (l);

■ i. Revising Alternates I, II, and III; and

■ j. Adding Alternate IV.

The revisions and additions read as follows:

52.219–9 Small Business Subcontracting Plan.

* * * * *

Small Business Subcontracting Plan (Nov 2016)

* * * * *

(b) * * *

Individual subcontracting plan means a subcontracting plan that covers the entire contract period (including option periods), applies to a specific contract, and has goals that are based on the offeror's planned subcontracting in support of the specific contract, except that indirect costs incurred for common or joint purposes may be allocated on a prorated basis to the contract.

Master subcontracting plan means a subcontracting plan that contains all the required elements of an individual subcontracting plan, except goals, and may be incorporated into individual subcontracting plans, provided the master subcontracting plan has been approved.

* * * * *

Total contract dollars means the final anticipated dollar value, including the dollar value of all options.

(c)(1) The Offeror, upon request by the Contracting Officer, shall submit and negotiate a subcontracting plan, where applicable, that separately addresses subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. If the Offeror is submitting an individual subcontracting plan, the plan must separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns, with a separate part for the basic contract and separate parts for each option (if any). The subcontracting plan shall be included in and made a part of the resultant contract. The subcontracting plan shall be negotiated within the time specified by the Contracting Officer. Failure to submit and negotiate the subcontracting plan shall make the Offeror ineligible for award of a contract.

(2)(i) The Contractor may accept a subcontractor's written representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business if the subcontractor represents that the size and socioeconomic status representations with its offer are current, accurate, and complete as of the date of the offer for the subcontract.

(ii) The Contractor may accept a subcontractor's representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business in the System for Award Management (SAM) if—

(A) The subcontractor is registered in SAM; and

(B) The subcontractor represents that the size and socioeconomic status representations made in SAM are current, accurate and complete as of the date of the offer for the subcontract.

(iii) The Contractor may not require the use of SAM for the purposes of representing size or socioeconomic status in connection with a subcontract.

(iv) In accordance with 13 CFR 121.411, 124.1015, 125.29, 126.900, and 127.700, a contractor acting in good faith is not liable for misrepresentations made by its subcontractors regarding the subcontractor's size or socioeconomic status.

(d) The Offeror's subcontracting plan shall include the following:

(1) Separate goals, expressed in terms of total dollars subcontracted, and as a percentage of total planned subcontracting dollars, for the use of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as subcontractors. For individual subcontracting plans, and if required by the Contracting Officer, goals shall also be expressed in terms of percentage of total contract dollars, in addition to the goals expressed as a percentage of total subcontract dollars. The Offeror shall include all subcontracts that contribute to contract performance, and may include a proportionate share of products and services that are normally allocated as indirect costs. In accordance with 43 U.S.C. 1626—

(i) Subcontracts awarded to an ANC or Indian tribe shall be counted towards the subcontracting goals for small business and small disadvantaged business concerns, regardless of the size or Small Business Administration certification status of the ANC or Indian tribe; and

(ii) Where one or more subcontractors are in the subcontract tier between the prime Contractor and the ANC or Indian tribe, the ANC or Indian tribe shall designate the appropriate Contractor(s) to count the subcontract towards its small business and small disadvantaged business subcontracting goals.

* * * * *

(2) A statement of—

(i) Total dollars planned to be subcontracted for an individual subcontracting plan; or the Offeror's total projected sales, expressed in dollars, and the total value of projected subcontracts to support the sales for a commercial plan;

* * * * *

(3) A description of the principal types of supplies and services to be subcontracted, and an identification of the types planned for subcontracting to—

* * * * *

(5) A description of the method used to identify potential sources for solicitation purposes (*e.g.,* existing company source lists, SAM, veterans service organizations, the National Minority Purchasing Council Vendor Information Service, the Research and Information Division of the Minority Business Development Agency in the Department of Commerce, or small, HUBZone, small disadvantaged, and women-owned small business trade associations). A firm may rely on the information contained in SAM as an accurate representation of a concern's size and ownership characteristics for the purposes of maintaining a small, veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged, and women-owned small business source list. Use of SAM as its source list does not relieve a firm of its responsibilities (*e.g.,* outreach, assistance, counseling, or publicizing subcontracting opportunities) in this clause.

(6) A statement as to whether or not the Offeror included indirect costs in establishing subcontracting goals, and a description of the method used to determine the proportionate share of indirect costs to be incurred with—

* * * * *

(7) The name of the individual employed by the Offeror who will administer the Offeror's subcontracting program, and a description of the duties of the individual.

(8) A description of the efforts the Offeror will make to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns have an equitable opportunity to compete for subcontracts.

(9) Assurances that the Offeror will include the clause of this contract entitled "Utilization of Small Business Concerns" in all subcontracts that offer further subcontracting opportunities, and that the Offeror will require all subcontractors (except small business concerns) that receive subcontracts in excess of $700,000 ($1.5 million for construction of any public facility) with further subcontracting possibilities to adopt a subcontracting plan that complies with the requirements of this clause.

(10) Assurances that the Offeror will—

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the Offeror with the subcontracting plan;

(iii) After November 30, 2017, include subcontracting data for each order when reporting subcontracting achievements for indefinite-delivery, indefinite-quantity contracts intended for use by multiple agencies;

(iv) Submit the Individual Subcontract Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at *http://www.esrs.gov.* The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by SBA as small disadvantaged businesses), women-owned small business concerns, and for NASA only, Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;

(v) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;

(vi) Provide its prime contract number, its DUNS number, and the email address of the Offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and

(vii) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the email address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

(11) * * *

(iv) * * *

(C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, service-disabled veteran-owned, and women-owned small business sources; and

* * * * *

(12) Assurances that the Offeror will make a good faith effort to acquire articles, equipment, supplies, services, or materials, or obtain the performance of construction work from the small business concerns that it used in preparing the bid or proposal, in the same or greater scope, amount, and quality used in preparing and submitting the bid or proposal. Responding to a request for a quote does not constitute use in preparing a bid or proposal. The Offeror used a small business concern in preparing the bid or proposal if—

(i) The Offeror identifies the small business concern as a subcontractor in the bid or proposal or associated small business subcontracting plan, to furnish certain supplies or perform a portion of the subcontract; or

(ii) The Offeror used the small business concern's pricing or cost information or technical expertise in preparing the bid or proposal, where there is written evidence of an intent or understanding that the small business concern will be awarded a subcontract for the related work if the Offeror is awarded the contract.

(13) Assurances that the Contractor will provide the Contracting Officer with a written explanation if the Contractor fails to acquire articles, equipment, supplies, services or materials or obtain the performance of construction work as described in (d)(12) of this clause. This written explanation must be submitted to the Contracting Officer within 30 days of contract completion.

(14) Assurances that the Contractor will not prohibit a subcontractor from discussing with the Contracting Officer any material matter pertaining to payment to or utilization of a subcontractor.

(e) * * *

(4) Confirm that a subcontractor representing itself as a HUBZone small business concern is certified by SBA as a HUBZone small business concern in accordance with 52.219–8(d)(2).

* * * * *

(6) For all competitive subcontracts over the simplified acquisition threshold in which a small business concern received a small business preference, upon determination of the successful subcontract offeror, prior to award of the subcontract the Contractor must inform each unsuccessful small business subcontract offeror in writing of the name and location of the apparent successful offeror and if the successful subcontract offeror is a small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concern.

(7) Assign each subcontract the NAICS code and corresponding size standard that best describes the principal purpose of the subcontract.

(f) A master subcontracting plan on a plant or division-wide basis that contains all the elements required by paragraph (d) of this clause, except goals, may be incorporated by reference as a part of the subcontracting plan required of the Offeror by this clause; provided—

(1) The master subcontracting plan has been approved;

(2) The Offeror ensures that the master subcontracting plan is updated as necessary and provides copies of the approved master subcontracting plan, including evidence of its approval, to the Contracting Officer; and

(3) Goals and any deviations from the master subcontracting plan deemed necessary by the Contracting Officer to satisfy the requirements of this contract are set forth in the individual subcontracting plan.

* * * * *

(i) A contract may have no more than one subcontracting plan. When a contract modification exceeds the subcontracting plan threshold in 19.702(a), or an option is exercised, the goals of the existing subcontracting plan shall be amended to reflect any new subcontracting opportunities. When the goals in a subcontracting plan are amended, these goal changes do not apply retroactively.

* * * * *

(k) The failure of the Contractor or subcontractor to comply in good faith with (1) the clause of this contract entitled "Utilization Of Small Business Concerns," or (2) an approved plan required by this clause, shall be a material breach of the contract and may be considered in any past performance evaluation of the Contractor.

(l) The Contractor shall submit ISRs and SSRs using the web-based eSRS at *http://www.esrs.gov.* Purchases from a corporation, company, or subdivision that is an affiliate of the Contractor or subcontractor are not included in these reports. Subcontract awards by affiliates shall be treated as subcontract awards by the Contractor. Subcontract award data reported by the Contractor and subcontractors shall be limited to awards made to their immediate next-tier subcontractors. Credit cannot be taken for awards made to lower tier subcontractors, unless the Contractor or subcontractor has been designated to receive a small business or small disadvantaged business credit from an ANC or Indian tribe. Only subcontracts involving performance in the United States or its outlying areas should be included in these reports with the exception of subcontracts under a contract awarded by the State Department or any other agency that has statutory or regulatory authority to require subcontracting plans for subcontracts performed outside the United States and its outlying areas.

(1) *ISR.* This report is not required for commercial plans. The report is required for each contract containing an individual subcontracting plan.

(i) The report shall be submitted semi-annually during contract performance for the periods ending March 31 and September 30. A report is also required for each contract within 30 days of contract completion. Reports are due 30 days after the close of each reporting period, unless otherwise directed by the Contracting Officer. Reports are required when due, regardless of whether there has been any subcontracting activity since the inception of the contract or the previous reporting period. When the Contracting Officer rejects an ISR, the Contractor shall submit a corrected report within 30 days of receiving the notice of ISR rejection.

(ii)(A) When a subcontracting plan contains separate goals for the basic contract and each option, as prescribed by FAR 19.704(c), the dollar goal inserted on this report shall be the sum of the base period through the current option; for example, for a report submitted after the second option is exercised, the dollar goal would be the sum of the goals for the basic contract, the first option, and the second option.

(B) If a subcontracting plan has been added to the contract pursuant to 19.702(a)(3) or 19.301–2(e), the Contractor's achievements must be reported in the ISR on a cumulative basis from the date of incorporation of the subcontracting plan into the contract.

(iii) When a subcontracting plan includes indirect costs in the goals, these costs must be included in this report.

(iv) The authority to acknowledge receipt or reject the ISR resides—

(A) In the case of the prime Contractor, with the Contracting Officer; and

(B) In the case of a subcontract with a subcontracting plan, with the entity that awarded the subcontract.

(2) *SSR.* (i) *Reports submitted under individual subcontracting plans.*

(A) This report encompasses all subcontracting under prime contracts and subcontracts with an executive agency, regardless of the dollar value of the subcontracts. This report also includes indirect costs on a prorated basis when the indirect costs are excluded from the subcontracting goals.

(B) The report may be submitted on a corporate, company or subdivision (*e.g.* plant or division operating as a separate profit center) basis, unless otherwise directed by the agency.

(C) If the Contractor or a subcontractor is performing work for more than one executive agency, a separate report shall be submitted to each executive agency covering only that agency's contracts, provided at least one of that agency's contracts is over $700,000 (over $1.5 million for construction of a public facility) and contains a subcontracting plan. For DoD, a consolidated report shall be submitted for all contracts awarded by military departments/agencies and/or subcontracts awarded by DoD prime contractors.

(D) The report shall be submitted annually by October 30 for the twelve month period ending September 30. When a Contracting Officer rejects an SSR, the Contractor shall submit a revised report within 30 days of receiving the notice of SSR rejection.

(E) Subcontract awards that are related to work for more than one executive agency shall be appropriately allocated.

(F) The authority to acknowledge or reject SSRs in eSRS, including SSRs submitted by subcontractors with subcontracting plans, resides with the Government agency awarding the prime contracts unless stated otherwise in the contract.

(ii) *Reports submitted under a commercial plan.*

(A) The report shall include all subcontract awards under the commercial plan in effect during the Government's fiscal year and all indirect costs.

(B) The report shall be submitted annually, within thirty days after the end of the Government's fiscal year.

(C) If a Contractor has a commercial plan and is performing work for more than one executive agency, the Contractor shall specify the percentage of dollars attributable to each agency.

(D) The authority to acknowledge or reject SSRs for commercial plans resides with the Contracting Officer who approved the commercial plan.

(End of clause)

Alternate I (Nov 2016). As prescribed in 19.708(b)(1)(i), substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c)(1) The apparent low bidder, upon request by the Contracting Officer, shall submit a subcontracting plan, where applicable, that separately addresses subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. If the bidder is submitting an individual subcontracting plan, the plan must separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns, with a separate part for the basic contract and separate parts for each option (if any). The plan shall be included in and made a part of the resultant contract. The subcontracting plan shall be submitted within the time specified by the Contracting Officer. Failure to submit the subcontracting plan shall make the bidder ineligible for the award of a contract.

Alternate II (Nov 2016). As prescribed in 19.708(b)(1)(ii), substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c)(1) Proposals submitted in response to this solicitation shall include a subcontracting plan that separately addresses subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. If the Offeror is submitting an individual subcontracting plan, the plan must separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns, with a separate part for the basic contract and separate parts for each option (if any). The plan shall be included in and made a part of the resultant contract. The subcontracting plan shall be negotiated within the time specified by the Contracting Officer. Failure to submit and negotiate a subcontracting plan shall make the Offeror ineligible for award of a contract.

Alternate III (Nov 2016). As prescribed in 19.708(b)(1)(iii), substitute the following paragraphs (d)(10) and (l) for paragraphs (d)(10) and (l) in the basic clause;

(d)(10) Assurances that the Offeror will—

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the Offeror with the subcontracting plan;

(iii) Submit Standard Form (SF) 294 Subcontracting Report for Individual Contract in accordance with paragraph (l) of this clause. Submit the Summary Subcontract Report (SSR), in accordance with paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at *http://www.esrs.gov.* The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by the Small Business Administration as small disadvantaged businesses), women-owned small business concerns, and for NASA only, Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations; and

(iv) Ensure that its subcontractors with subcontracting plans agree to submit the SF 294 in accordance with paragraph (l) of this clause. Ensure that its subcontractors with subcontracting plans agree to submit the SSR in accordance with paragraph (l) of this clause using the eSRS.

(l) The Contractor shall submit a SF 294. The Contractor shall submit SSRs using the web-based eSRS at *http://www.esrs.gov.* Purchases from a corporation, company, or subdivision that is an affiliate of the Contractor or subcontractor are not included in these reports. Subcontract awards by affiliates shall be treated as subcontract awards by the Contractor. Subcontract award data reported by the Contractor and subcontractors shall be limited to awards made to their immediate next-tier subcontractors. Credit cannot be taken for awards made to lower tier subcontractors, unless the Contractor or subcontractor has been designated to receive a small business or small disadvantaged business credit from an ANC or Indian tribe. Only subcontracts involving performance in the U.S. or its outlying areas should be included in these reports with the exception of subcontracts under a contract awarded by the State Department or any other agency that has statutory or regulatory authority to require subcontracting plans for subcontracts performed outside the United States and its outlying areas.

(1) *SF 294.* This report is not required for commercial plans. The report is required for each contract containing an individual subcontracting plan. For Contractors the report shall be submitted to the Contracting Officer, or as specified elsewhere in this contract. In the case of a subcontract with a subcontracting plan, the report shall be submitted to the entity that awarded the subcontract.

(i) The report shall be submitted semi-annually during contract performance for the periods ending March 31 and September 30. A report is also required for each contract within 30 days of contract completion. Reports are due 30 days after the close of each reporting period, unless otherwise directed by the Contracting Officer. Reports are required when due, regardless of whether there has been any subcontracting activity since the inception of the contract or the previous reporting period. When a Contracting Officer rejects a report, the Contractor shall submit a revised report within 30 days of receiving the notice of report rejection.

(ii)(A) When a subcontracting plan contains separate goals for the basic contract and each option, as prescribed by FAR 19.704(c), the dollar goal inserted on this report shall be the sum of the base period through the current option; for example, for a report submitted after the second option is exercised, the dollar goal would be the sum of the goals for the basic contract, the first option, and the second option.

(B) If a subcontracting plan has been added to the contract pursuant to 19.702(a)(3) or 19.301–2(e), the Contractor's achievements must be reported in the report on a cumulative basis from the date of incorporation of the subcontracting plan into the contract.

(iii) When a subcontracting plan includes indirect costs in the goals, these costs must be included in this report.

(2) *SSR.* (i)*Reports submitted under individual subcontracting plans.*

(A) This report encompasses all subcontracting under prime contracts and subcontracts with an executive agency, regardless of the dollar value of the subcontracts. This report also includes indirect costs on a prorated basis when the indirect costs are excluded from the subcontracting goals.

(B) The report may be submitted on a corporate, company or subdivision (*e.g.*, plant or division operating as a separate profit center) basis, unless otherwise directed by the agency.

(C) If the Contractor and/or a subcontractor is performing work for more than one executive agency, a separate report shall be submitted to each executive agency covering only that agency's contracts, provided at least one of that agency's contracts is over $700,000 (over $1.5 million for construction of a public facility) and contains a subcontracting plan. For DoD, a consolidated report shall be submitted for all contracts awarded by military departments/agencies and/or subcontracts awarded by DoD prime contractors.

(D) The report shall be submitted annually by October 30, for the twelve month period ending September 30. When a Contracting Officer rejects an SSR, the Contractor is required to submit a revised SSR within 30 days of receiving the notice of report rejection.

(E) Subcontract awards that are related to work for more than one executive agency shall be appropriately allocated.

(F) The authority to acknowledge or reject SSRs in the eSRS, including SSRs submitted by subcontractors with subcontracting plans, resides with the Government agency awarding the prime contracts unless stated otherwise in the contract.

(ii) *Reports submitted under a commercial plan.*

(A) The report shall include all subcontract awards under the commercial plan in effect during the Government's fiscal year and all indirect costs.

(B) The report shall be submitted annually, within 30 days after the end of the Government's fiscal year.

(C) If a Contractor has a commercial plan and is performing work for more than one executive agency, the Contractor shall specify the percentage of dollars attributable to each agency.

(D) The authority to acknowledge or reject SSRs for commercial plans resides with the Contracting Officer who approved the commercial plan.

Alternate IV (Nov 2016). As prescribed in 19.708(b)(1)(iv), substitute the following paragraphs (c) and (d) for paragraphs (c) and (d) of the basic clause:

(c)(1) The Contractor, upon request by the Contracting Officer, shall submit and negotiate a subcontracting plan, where applicable, that separately addresses subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. If the Contractor is submitting an individual subcontracting plan, the plan shall separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns, with a separate part for the basic contract and separate parts for each option (if any). The subcontracting plan shall be incorporated into the contract. The subcontracting plan shall be negotiated within the time specified by the Contracting Officer. The subcontracting plan does not apply retroactively.

(2)(i) The prime Contractor may accept a subcontractor's written representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business if the subcontractor represents that the size and socioeconomic status representations with its offer are current, accurate, and complete as of the date of the offer for the subcontract.

(ii) The Contractor may accept a subcontractor's representations of its size and socioeconomic status as a small business, small disadvantaged business, veteran-owned small business, service-disabled veteran-owned small business, or a women-owned small business in the System for Award Management (SAM) if—

(A) The subcontractor is registered in SAM; and

(B) The subcontractor represents that the size and socioeconomic status representations made in SAM are current, accurate and complete as of the date of the offer for the subcontract.

(iii) The Contractor may not require the use of SAM for the purposes of representing size or socioeconomic status in connection with a subcontract.

(iv) In accordance with 13 CFR 121.411, 124.1015, 125.29, 126.900, and 127.700, a contractor acting in good faith is not liable for misrepresentations made by its subcontractors regarding the subcontractor's size or socioeconomic status.

(d) The Contractor's subcontracting plan shall include the following:

(1) Separate goals, expressed in terms of total dollars subcontracted and as a percentage of total planned subcontracting dollars, for the use of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as subcontractors. For individual subcontracting plans, and if required by the Contracting Officer, goals shall also be expressed in terms of percentage of total contract dollars, in addition to the goals expressed as a percentage of total subcontract dollars. The Contractor shall include all subcontracts that contribute to contract performance, and may include a proportionate share of products and services that are normally allocated as indirect costs. In accordance with 43 U.S.C. 1626—

(i) Subcontracts awarded to an ANC or Indian tribe shall be counted towards the subcontracting goals for small business and small disadvantaged business concerns, regardless of the size or Small Business Administration certification status of the ANC or Indian tribe; and

(ii) Where one or more subcontractors are in the subcontract tier between the prime Contractor and the ANC or Indian tribe, the ANC or Indian tribe shall designate the appropriate Contractor(s) to count the subcontract towards its small business and small disadvantaged business subcontracting goals.

(A) In most cases, the appropriate Contractor is the Contractor that awarded the subcontract to the ANC or Indian tribe.

(B) If the ANC or Indian tribe designates more than one Contractor to count the subcontract toward its goals, the ANC or Indian tribe shall designate only a portion of the total subcontract award to each Contractor. The sum of the amounts designated to various Contractors cannot exceed the total value of the subcontract.

(C) The ANC or Indian tribe shall give a copy of the written designation to the Contracting Officer, the Contractor, and the subcontractors in between the prime Contractor and the ANC or Indian tribe within 30 days of the date of the subcontract award.

(D) If the Contracting Officer does not receive a copy of the ANC's or the Indian tribe's written designation within 30 days of the subcontract award, the Contractor that awarded the subcontract to the ANC or Indian tribe will be considered the designated Contractor.

(2) A statement of—

(i) Total dollars planned to be subcontracted for an individual subcontracting plan; or the Contractor's total projected sales, expressed in dollars, and the total value of projected subcontracts to support the sales for a commercial plan;

(ii) Total dollars planned to be subcontracted to small business concerns (including ANC and Indian tribes);

(iii) Total dollars planned to be subcontracted to veteran-owned small business concerns;

(iv) Total dollars planned to be subcontracted to service-disabled veteran-owned small business;

(v) Total dollars planned to be subcontracted to HUBZone small business concerns;

(vi) Total dollars planned to be subcontracted to small disadvantaged business concerns (including ANCs and Indian tribes); and

(vii) Total dollars planned to be subcontracted to women-owned small business concerns.

(3) A description of the principal types of supplies and services to be subcontracted, and an identification of the types planned for subcontracting to—

(i) Small business concerns;

(ii) Veteran-owned small business concerns;

(iii) Service-disabled veteran-owned small business concerns;

(iv) HUBZone small business concerns;

(v) Small disadvantaged business concerns; and

(vi) Women-owned small business concerns.

(4) A description of the method used to develop the subcontracting goals in paragraph (d)(1) of this clause.

(5) A description of the method used to identify potential sources for solicitation purposes (*e.g.,* existing company source lists, SAM, veterans service organizations, the National Minority Purchasing Council Vendor Information Service, the Research and Information Division of the Minority Business Development Agency in the Department of Commerce, or small, HUBZone, small disadvantaged, and women-owned small business trade associations). The Contractor may rely on the information contained in SAM as an accurate representation of a concern's size and ownership characteristics for the purposes of maintaining a small, veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged, and women-owned small business source list. Use of SAM as its source list does not relieve a firm of its responsibilities (*e.g.,* outreach, assistance, counseling, or publicizing subcontracting opportunities) in this clause.

(6) A statement as to whether or not the Contractor included indirect costs in

establishing subcontracting goals, and a description of the method used to determine the proportionate share of indirect costs to be incurred with—

(i) Small business concerns (including ANC and Indian tribes);

(ii) Veteran-owned small business concerns;

(iii) Service-disabled veteran-owned small business concerns;

(iv) HUBZone small business concerns;

(v) Small disadvantaged business concerns (including ANC and Indian tribes); and

(vi) Women-owned small business concerns.

(7) The name of the individual employed by the Contractor who will administer the Contractor's subcontracting program, and a description of the duties of the individual.

(8) A description of the efforts the Contractor will make to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns have an equitable opportunity to compete for subcontracts.

(9) Assurances that the Contractor will include the clause of this contract entitled "Utilization of Small Business Concerns" in all subcontracts that offer further subcontracting opportunities, and that the Contractor will require all subcontractors (except small business concerns) that receive subcontracts in excess of $700,000 ($1.5 million for construction of any public facility) with further subcontracting possibilities to adopt a subcontracting plan that complies with the requirements of this clause.

(10) Assurances that the Contractor will—

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the Contractor with the subcontracting plan;

(iii) After November 30, 2017, include subcontracting data for each order when reporting subcontracting achievements for an indefinite-delivery, indefinite-quantity contract intended for use by multiple agencies;

(iv) Submit the Individual Subcontract Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at *http://www.esrs.gov.* The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by SBA as small disadvantaged businesses), women-owned small business concerns, and for NASA only, Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;

(v) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;

(vi) Provide its prime contract number, its DUNS number, and the email address of the Contractor's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and

(vii) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the email address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

(11) A description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing source lists; and a description of the Contractor's efforts to locate small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

(i) Source lists (*e.g.*, SAM), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.

(ii) Organizations contacted in an attempt to locate sources that are small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.

(iii) Records on each subcontract solicitation resulting in an award of more than $150,000, indicating—

(A) Whether small business concerns were solicited and, if not, why not;

(B) Whether veteran-owned small business concerns were solicited and, if not, why not;

(C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;

(D) Whether HUBZone small business concerns were solicited and, if not, why not;

(E) Whether small disadvantaged business concerns were solicited and, if not, why not;

(F) Whether women-owned small business concerns were solicited and, if not, why not; and

(G) If applicable, the reason award was not made to a small business concern.

(iv) Records of any outreach efforts to contact—

(A) Trade associations;

(B) Business development organizations;

(C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, service-disabled veteran-owned, and women-owned small business sources; and

(D) Veterans service organizations.

(v) Records of internal guidance and encouragement provided to buyers through—

(A) Workshops, seminars, training, *etc.*; and

(B) Monitoring performance to evaluate compliance with the program's requirements.

(vi) On a contract-by-contract basis, records to support award data submitted by the Contractor to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

(12) Assurances that the Contractor will make a good faith effort to acquire articles, equipment, supplies, services, or materials, or obtain the performance of construction work from the small business concerns that it used in preparing the proposal for the modification, in the same or greater scope, amount, and quality used in preparing and submitting the modification proposal. Responding to a request for a quote does not constitute use in preparing a proposal. The Contractor used a small business concern in preparing the proposal for a modification if—

(i) The Contractor identifies the small business concern as a subcontractor in the proposal or associated small business subcontracting plan, to furnish certain supplies or perform a portion of the subcontract; or

(ii) The Contractor used the small business concern's pricing or cost information or technical expertise in preparing the proposal, where there is written evidence of an intent or understanding that the small business concern will be awarded a subcontract for the related work when the modification is executed.

(13) Assurances that the Contractor will provide the Contracting Officer with a written explanation if the Contractor fails to acquire articles, equipment, supplies, services or materials or obtain the performance of construction work as described in (d)(12) of this clause. This written explanation must be submitted to the Contracting Officer within 30 days of contract completion.

(14) Assurances that the Contractor will not prohibit a subcontractor from discussing with the contracting officer any material matter pertaining to the payment to or utilization of a subcontractor.

■ 20. Amend section 52.244–6 by revising the date of the clause and the first sentence of paragraph (c)(1)(iii) to read as follows:

52.244–6 Subcontracts for Commercial Items.

* * * * *

Subcontracts for Commercial Items (Nov 2016)

* * * * *

(c)(1) * * *

(iii) 52.219–8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), if the subcontract offers further subcontracting opportunities.

* * * * *

[FR Doc. 2016–16245 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 15, 16, 31, 42, and 52

[FAC 2005–89; FAR Case 2014–023; Item II; Docket No. 2014–0023, Sequence No. 1]

RIN 9000–AN17

Federal Acquisition Regulation; OMB Circular Citation Update

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to update outdated Office of Management and Budget (OMB) Circular citation references.

DATES: *Effective:* August 15, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Kathlyn J. Hopkins, Procurement Analyst, at 202–969–7226, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–89, FAR Case 2014–023.

SUPPLEMENTARY INFORMATION:

I. Background

On December 26, 2013, the Office of Management and Budget (OMB) published new guidance at 2 CFR part 200 entitled Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (OMB Uniform Guidance); this became effective on December 26, 2014, after Federal agencies adopted the guidance as a set of binding regulations. This new OMB Uniform Guidance supersedes and streamlines requirements from OMB Circulars A–21, A–87, A–89, A–102, A–110, A–122, and A–133, and the guidance in Circular A–50 on Audit Followup. As such, this final rule replaces OMB citations in the FAR to the circulars cited above that have been replaced by this new OMB Uniform Guidance, and cross references to new terminology in the OMB Uniform Guidance.

The cost principles under OMB's Uniform Guidance apply to contracts with non-profits, educational institutions, state and local governments, and Indian tribal governments. All other FAR contractual requirements (*e.g.,* contract administration, audit) take precedence over the OMB Uniform Guidance when there is a conflict.

This rule also creates a definition with an abbreviated title in FAR section 2.101 for FAR citations to this OMB Uniform Guidance.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

"Publication of proposed regulations," 41 U.S.C. 1707, is the statute that applies to the publication of the FAR. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it merely replaces outdated OMB Circular references in the FAR with current references that do not have a significant effect on contractors or offerors.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant FAR revision within the meaning of FAR 1.501–1 and 41 U.S.C. 1707 and does not require publication for public comment.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 2, 15, 16, 31, 42, and 52

Government procurement.

Dated: June 30, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 2, 15, 16, 31, 42, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 15, 16, 31, 42, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 2. Amend section 2.101 in paragraph (b)(2) by adding in alphabetical order the definition "OMB Uniform Guidance at 2 CFR part 200" to read as follows:

2.101 [Amended]

* * * * *

(b) * * *

(2) * * *

OMB Uniform Guidance at 2 CFR part 200 is the abbreviated title for Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200), which supersedes OMB Circulars A–21, A–87, A–89, A–102, A–110, A–122, and A–133, and the guidance in Circular A–50 on Audit Followup.

* * * * *

PART 15—CONTRACTING BY NEGOTIATION

15.209 [Amended]

■ 3. Amend section 15.209 by removing from paragraph (b)(1) introductory text, "OMB Circular No. A–133" and adding "Audit Requirements in the OMB Uniform Guidance at 2 CFR part 200, subpart F" in its place.

PART 16—TYPES OF CONTRACTS

16.307 [Amended]

■ 4. Amend section 16.307 by removing from paragraph (a)(5) "OMB Circular No. A–122" and adding "the OMB Uniform Guidance at 2 CFR part 200, appendix VIII" in its place.

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

■ 5. Amend section 31.104 by revising the introductory text to read as follows:

31.104 Contracts with educational institutions.

This category includes all contracts and contract modifications for research and development, training, and other work performed by educational institutions (defined as institutions of higher educations in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001).

* * * * *

31.105 [Amended]

■ 6. Amend section 31.105 by removing from paragraph (a) "OMB Circular A–122 (see 31–108)" and adding "OMB Uniform Guidance at 2 CFR part 200, appendix VIII (see 31.108)" in its place.

■ 7. Revise section 31.108 to read as follows:

31.108 Contracts with nonprofit organizations.

Subpart 31.7 provides principles and standards for determining costs applicable to contracts with nonprofit organizations other than educational institutions (see subpart 31.3), State and local governments (see subpart 31.6), and those nonprofit organizations exempted under the OMB Uniform Guidance at 2 CFR part 200, appendix VIII (see subpart 31.2 for the cost principles applicable to nonprofit organizations exempt from the cost principles in the OMB Uniform Guidance at 2 CFR part 200).

■ 8. Revise section 31.302 to read as follows:

31.302 General.

The OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III, provides principles for determining the costs applicable to research and development, training, and other work performed by educational institutions (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001) under contracts with the Government.

■ 9. Amend section 31.303 by revising paragraph (a) to read as follows:

31.303 Requirements.

(a) Contracts that refer to this subpart 31.3 for determining allowable costs under contracts with educational institutions (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001) shall be deemed to refer to, and shall have the allowability of costs determined by the contracting officer in accordance with, the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III, in effect on the date of the contract.

* * * * *

31.602 [Amended]

■ 10. Amend section 31.602 by removing "Office of Management and Budget (OMB) Circular No. A–87, Cost Principles for State and Local Governments, Revised," and adding "The OMB Uniform Guidance at 2 CFR part 200, subpart E and appendices V and VII" in its place.

31.603 [Amended]

■ 11. Amend section 31.603 by removing from paragraph (a) "the revision of OMB Circular A–87 which is" and adding "the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendices V and VII," in its place.

■ 12. Revise section 31.702 to read as follows:

The OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix IV, sets forth principles for determining the costs applicable to work performed by nonprofit organizations (as defined in the OMB Uniform Guidance at 2 CFR part 200) under contracts (as well as grants and other agreements) with the Government. See 31.108 for exceptions to the cost principles for nonprofit organizations.

31.703 [Amended]

■ 13. Amend section 31.703 by removing from paragraph (a) "the revision of OMB circular A–122" and adding "the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix IV" in its place.

PART 42—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 14. Amend section 42.003 by revising paragraph (a) to read as follows:

42.003 Cognizant Federal agency.

(a) For contractors other than educational institutions and nonprofit organizations, the cognizant Federal agency normally will be the agency with the largest dollar amount of negotiated contracts, including options. For educational institutions (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001) and nonprofit organizations (as defined in the OMB Uniform Guidance at 2 CFR part 200), the cognizant Federal agency for indirect costs is established according to the OMB Uniform Guidance at 2 CFR part 200, appendices III and IV, respectively.

* * * * *

■ 15. Amend section 42.101 by revising paragraph (b) to read as follows:

42.101 Contract audit responsibilities.

* * * * *

(b) Normally, for contractors other than educational institutions and nonprofit organizations, the Defense Contract Audit Agency (DCAA) is the responsible Government audit agency. However, there may be instances where an agency other than DCAA desires cognizance of a particular contractor. In those instances, the two agencies shall agree on the most efficient and economical approach to meet contract audit requirements. For educational institutions (defined as institutions of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001) and nonprofit organizations (as defined in the OMB Uniform Guidance at 2 CFR part 200), audit cognizance will be determined according to the provisions of the OMB Uniform Guidance at 2 CFR part 200, subpart F.

■ 16. Amend section 42.703–2 by revising paragraphs (b)(2)(ii) through (iv) to read as follows:

42.703–2 Certificate of indirect costs.

* * * * *

(b) * * *

(2) * * *

(ii) A State or local government subject to the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendices V and VII;

(iii) An educational institution (defined as an institution of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A, and 20 U.S.C. 1001) subject to the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III; and

(iv) A nonprofit organization (as defined in the OMB Uniform Guidance at 2 CFR part 200) subject to the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix IV.

* * * * *

■ 17. Amend section 42.705–3 by revising paragraphs (a)(2) and (3); and adding paragraph (b)(8) to read as follows:

42.705–3 Educational institutions.

(a) * * *

(2) The OMB Uniform Guidance at 2 CFR part 200, appendix III assigns each educational institution (defined as an institution of higher education in the OMB Uniform Guidance at 2 CFR part

200, subpart A, and 20 U.S.C. 1001) to a single Government agency for the negotiation of indirect cost rates and provides that those rates shall be accepted by all Federal agencies. Cognizant Government agencies and educational institutions are listed in the Directory of Federal Contract Audit Offices (see 42.103).

(3) The cognizant agency for indirect costs shall establish the billing rates and final indirect cost rates at the educational institution (defined as an institution of higher education in 2 CFR 200, subpart A, and 20 U.S.C. 1001) consistent with the requirements of this subpart, Subpart 31.3, and the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III. The agency shall follow the procedures outlined in 42.705–1(b).

* * * * *

(b) * * *

(8) The OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III, provides additional guidance on how long predetermined rates may be used.

■ 18. Revise section 42.705–4 to read as follows:

42.705–4 State and local governments.

The OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix V, concerning cost principles for state and local governments (see Subpart 31.6) establishes the cognizant agency concept and the procedures for determining a cognizant agency for approving State and local government indirect costs associated with federally-funded programs and activities. The indirect cost rates negotiated and approved by the cognizant agency for indirect costs will be used by all Federal agencies that also award contracts to these same State and local governments.

42.705–5 [Amended]

■ 19. Amend section 42.705–5 by removing "OMB Circular No. A–122" and adding "the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix IV; but see appendix VIII for nonprofit organizations exempt from subpart E)" in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 20. Amend section 52.215–2 by revising the date of Alternate II and paragraph (h) to read as follows:

52.215–2 Audit and Records-Negotiation.

* * * * *

Alternate II (Aug 2016). * * *

(h) The provisions of the OMB Uniform Guidance at 2 CFR part 200, subpart F apply to this contract.

* * * * *

■ 21. Amend section 52.230–5 by revising the date of the clause and paragraphs (a)(1) and (2) and (a)(4)(iv) to read as follows:

52.230–5 Cost Accounting Standards—Educational Institution.

* * * * *

Cost Accounting Standards—Educational Institution (Aug 2016)

(a) * * *

(1) (*CAS-covered Contracts only*). If a business unit of an educational institution (defined as an institution of higher education in the OMB Uniform Guidance at 2 CFR part 200, subpart A and 20 U.S.C. 1001) is required to submit a Disclosure Statement, disclose in writing the Contractor's cost accounting practices as required by 48 CFR 9003.202–1 through 9903.202–5, including methods of distinguishing direct costs from indirect costs and the basis used for accumulating and allocating indirect costs. The practices disclosed for this contract shall be the same as the practices currently disclosed and applied on all other contracts and subcontracts being performed by the Contractor and which contain a Cost Accounting Standards (CAS) clause. If the Contractor has notified the Contracting Officer that the Disclosure Statement contains trade secrets, and commercial or financial information which is privileged and confidential, the Disclosure Statement shall be protected and shall not be released outside of the Government.

(2) Follow consistently the Contractor's cost accounting practices in accumulating and reporting contract performance cost data concerning this contract. If any change in cost accounting practices is made for the purposes of any contract or subcontract subject to CAS requirements, the change must be applied prospectively to this contract and the Disclosure Statement, if required, must be amended accordingly. If an accounting principle change mandated under OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III, requires that a change in the Contractor's cost accounting practices be made after the date of this contract award, the change must be applied prospectively to this contract and the Disclosure Statement, if required, must be amended accordingly. If the contract price or cost allowance of this contract is affected by such changes, adjustment shall be made in accordance with paragraph (a)(4) or (a)(5) of this clause, as appropriate.

* * * * *

(4) * * *

(iv) Agree to an equitable adjustment as provided in the Changes clause of this contract, if the contract cost is materially affected by an accounting principle amendment required under the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix III, which, on becoming effective after the date of contract award, requires the Contractor to make a change to the Contractor's established cost accounting practices.

* * * * *

■ 22. Amend section 52.249–5 by revising the date of the clause and paragraph (f) to read as follows:

52.249–5 Termination for Convenience of the Government (Educational and Other Nonprofit Institutions).

* * * * *

Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (Aug 2016)

* * * * *

(f) The cost principles and procedures in subpart 31.3 of the Federal Acquisition Regulation (FAR), Contracts with Educational Institutions (defined as institutions of higher education in the OMB Uniform Guidance in 2 CFR part 200, subpart A, and 20 U.S.C. 1001), as in effect on the date of the contract, shall govern all costs claimed, agreed to, or determined under this clause; however, if the Contractor is not an educational institution and is a nonprofit organization (as defined in the OMB Uniform Guidance at 2 CFR part 200), the cost principles and procedures in subpart 31.7 of the FAR, Contracts with Nonprofit Organizations, shall apply; unless the Contractor is a nonprofit institution listed in the OMB Uniform Guidance at 2 CFR part 200, appendix VIII, as exempted from the cost principles in subpart E, in which case the cost principles at FAR 31.2 for commercial organizations shall apply to such contractor.

[FR Doc. 2016–16246 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 8

[FAC 2005–89; FAR Case 2016–008; Item III; Docket No. 2016–0008; Sequence No 1]

RIN 9000–AN22

Federal Acquisition Regulation; FPI Blanket Waiver Threshold

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to increase the blanket waiver threshold for small dollar-value purchases from Federal Prison Industries (FPI) by Federal agencies.

DATES: *Effective:* August 15, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, at (703) 605–2868, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–89, FAR Case 2016–008.

SUPPLEMENTARY INFORMATION:

I. Background

Federal Prison Industries, Inc. (FPI), also known by its trade name, UNICOR, is governed by a six-member Board of Directors. The members are appointed by the President and, by statute, represent industry, labor, retailers and consumers, agriculture, the Secretary of Defense, and the Attorney General. On March 3, 2016, FPI's Board of Directors adopted a resolution increasing the blanket waiver threshold for small dollar-value purchases from FPI by Federal agencies from $3,000 to $3,500. The increase coincides with the increase in the micro-purchase threshold. This final rule amends the FAR to reflect the threshold increase from $3,000 to $3,500. No waiver is required to buy from an alternative source below $3,500. Customers may, however, still purchase from FPI at, or below, this threshold, if they so choose.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

"Publication of proposed regulations," 41 U.S.C. 1707, is the statute that applies to the publication of the FAR. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it only updates the threshold, consistent with the inflationary adjustment to the micro-purchase threshold, in order to conform to the decision made by the FPI Board of Directors. Additionally, this final rule is expected to be of benefit to industry because it makes available certain procurements to which industry did not previously have access, *i.e.,* listed items totaling $3,000.01 to $3,500.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This final rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant FAR revision within the meaning of FAR 1.501–1 and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 8

Government procurement.

Dated: June 30, 2016.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 8 as set forth below:

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICE

■ 1. The authority citation for 48 CFR part 8 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

8.605 [Amended]

■ 2. Amend section 8.605 by removing from paragraph (e) "$3,000" and adding "$3,500" in its place.

[FR Doc. 2016–16247 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 53

[FAC 2005–89; FAR Case 2015–025; Item IV; Docket No. 2015–0025, Sequence No. 1]

RIN 9000–AN11

Federal Acquisition Regulation; Revision to Standard Forms for Bonds

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule to amend five Standard Forms prescribed by the Federal Acquisition Regulation (FAR) for contracts involving bonds and other financial protections. The revisions are aimed at clarifying liability limitations and expanding the options for organization types.

DATES: *Effective:* August 15, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Kathlyn J. Hopkins, Procurement Analyst, at 202–969–7226, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–89, FAR Case 2015–025.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 80 FR 63485 on October 20, 2015, soliciting public comments on clarifying liability limitations and expanding the options for organization types on Standard Forms (SFs) 24, 25, 25A, 34, and 35. The proposed rule addressed concerns that surety bond producers may be adversely affected by differing Federal Agency views on the proper type of organization to indicate on these Standard Forms when the subject business was a limited liability company (LLC), an increasingly prevalent form of business in the construction industry. The proposed rule added a box labelled "Other: (Specify)" to the "Type of Organization" block on each of the five forms (SFs 24, 25, 25A, 34, and 35) in order to expand the range of business types to include not just LLCs, but others, as they evolve.

In addition, given recent questions from the construction industry regarding the appropriate value to report in the "Liability Limit" block on these Standard Forms, the proposed rule added clarifying instructions to the appropriate SFs (24, 25, and 25A). Finally, the proposed rule made various editorial corrections to the existing instructions.

Three respondents submitted public comments.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments is provided as follows:

A. Summary of Significant Changes

There were no changes made to the rule as a result of the comments received.

B. Analysis of Public Comments

1. Support for the Rule

Comment: Three respondents expressed support for the changes, highlighting their helpfulness to the procurement process, both by reducing confusion and by promoting efficient completion of forms. Moreover, two respondents affirmed that LLCs were a common type of business within the construction industry.

Response: The Government notes the public support for this rule.

2. Clarification of Liability Limit

Comment: One respondent, while applauding the improvements proposed for the forms' instructions, suggested additional clarifications. The respondent noted that sureties that provide bonds must hold a Certificate of Authority, and be identified as such in the U.S. Treasury Circular 570, which sets forth the underwriting limitations for each company. Pursuant to 31 CFR 223.11, a surety bond producer may write a bond in excess of its underwriting limitation if exceptions such as co-surety arrangements or reinsurance coverages exist. The respondent's specific concern was that a contracting officer might, upon comparing the amount in the "Liability Limit" block to the surety producer's underwriting limit, reject the bond without exploring the applicability of exceptions.

Response: The Government appreciates this concern, but notes that the proposed rule included instructions that clearly differentiate between individual sureties and co-surety arrangements, and how to complete the "Liability Limit" block in each case. Additionally, the instructions refer to the Treasury's list (Circular 570). Note (b) in Circular 570 specifically addresses the relationship between penal sum (face amount) and underwriting limitations, as well as exceptions and protections (co-insurance, reinsurance, or other methods in accordance with 31 CFR 223.10 and 223.11).

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

> The final rule amends five Standard Forms to provide more choices for organization types on five Standard Forms and to clarify instructions; the action's objective is to make the forms more reflective of current forms of business in the construction industry.
>
> There were no significant issues raised by the public in response to the Initial Regulatory Flexibility Analysis provided in the proposed rule.
>
> The final rule applies to all entities, both small and other than small, performing as contractors or subcontractors on U.S. Government contracts that require bonds and other financial protections. The Federal Procurement Data System indicates that the U.S. Government awarded 3,495 new construction contracts that required bonds and other financial protections from October 1, 2014 through August 4, 2015. Approximately 78 percent (2,711) of the total awards (3,495) were awarded to small entities (comprised of 1,687 unique small entities).
>
> There are no reporting or recordkeeping requirements associated with this rule. There were no significant alternatives identified that would meet the objective of the rule. However, the small entities will not be materially affected by this rule, as it simply allows all businesses to choose from a broader array of organization types.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

This rule affects the information collection requirements in the provisions at FAR 28.1 and 28.2; 52.228–1; 52.228–2; 52.228–13, 52.228–15; and 52.228–16, currently approved under OMB Control Number 9000–0045, titled: Bid Guarantees, Performance, and Payments Bonds, in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible, because this rule simply provides additional choices for offerors in characterizing their organization types on SFs 24, 25, 25A, 34, and 35, as well as clarifying what offerors should specify in terms of liability limits.

List of Subjects in 48 CFR Part 53

Government procurement.

Dated: June 30, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 53 as set forth below:

■ 1. The authority citation for 48 CFR part 53 continues to read as follows:

PART 53—FORMS

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

■ 2. Amend section 53.228 by revising paragraphs (a) through (g) to read as follows:

53.228 Bonds and insurance.

* * * * *

(a) *SF 24 (Rev. 8/2016) Bid Bond.* (See 28.106–1.) SF 24 is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

(b) *SF 25 (Rev. 8/2016) Performance Bond.* (See 28.106–1(b).) SF 25 is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

(c) *SF 25A (Rev. 8/2016) Payment Bond.* (See 28.106–1(c).) SF 25A is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

(d) *SF 25B (Rev. 10/83), Continuation Sheet (For Standard Forms 24, 25, and 25A)* (See 28.106–1(d).) This form can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

(e) *SF 28 (Rev. 6/03) Affidavit of Individual Surety.* (See 28.106–1(e) and 28.203(b).) SF 28 is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

(f) *SF 34 (Rev. (8/2016) Annual Bid Bond.* (See 28.106–1(f).) SF 34 is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

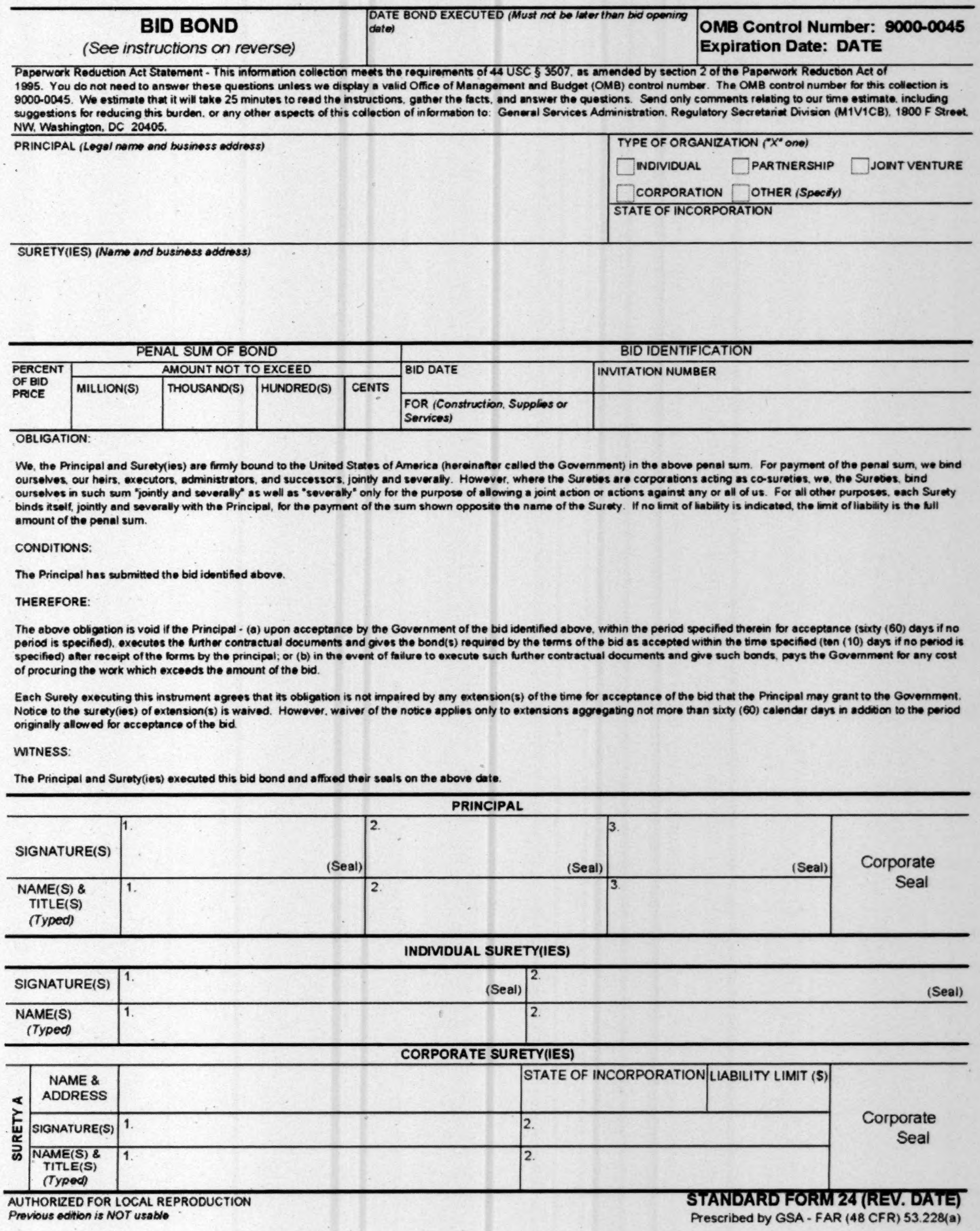
(g) *SF 35 (Rev. 8/2016) Annual Performance Bond.* (See 28.106–1.) SF 35 is authorized for local reproduction and can be found in the GSA Forms Library at *http://www.gsa.gov/forms.*

* * * * *

■ 3. Revise section 53.301–24 to read as follows:

53.301–24 Bid Bond.

BILLING CODE 6820–14–P



BID BOND *(See instructions on reverse)*	DATE BOND EXECUTED *(Must not be later than bid opening date)*	**OMB Control Number: 9000-0045** **Expiration Date: DATE**

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 USC § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0045. We estimate that it will take 25 minutes to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

PRINCIPAL *(Legal name and business address)*	TYPE OF ORGANIZATION *("X" one)* ☐ INDIVIDUAL ☐ PARTNERSHIP ☐ JOINT VENTURE ☐ CORPORATION ☐ OTHER *(Specify)*
	STATE OF INCORPORATION

SURETY(IES) *(Name and business address)*

PENAL SUM OF BOND					BID IDENTIFICATION	
PERCENT OF BID PRICE	AMOUNT NOT TO EXCEED				BID DATE	INVITATION NUMBER
	MILLION(S)	THOUSAND(S)	HUNDRED(S)	CENTS	FOR *(Construction, Supplies or Services)*	

OBLIGATION:

We, the Principal and Surety(ies) are firmly bound to the United States of America (hereinafter called the Government) in the above penal sum. For payment of the penal sum, we bind ourselves, our heirs, executors, administrators, and successors, jointly and severally. However, where the Sureties are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum "jointly and severally" as well as "severally" only for the purpose of allowing a joint action or actions against any or all of us. For all other purposes, each Surety binds itself, jointly and severally with the Principal, for the payment of the sum shown opposite the name of the Surety. If no limit of liability is indicated, the limit of liability is the full amount of the penal sum.

CONDITIONS:

The Principal has submitted the bid identified above.

THEREFORE:

The above obligation is void if the Principal - (a) upon acceptance by the Government of the bid identified above, within the period specified therein for acceptance (sixty (60) days if no period is specified), executes the further contractual documents and gives the bond(s) required by the terms of the bid as accepted within the time specified (ten (10) days if no period is specified) after receipt of the forms by the principal; or (b) in the event of failure to execute such further contractual documents and give such bonds, pays the Government for any cost of procuring the work which exceeds the amount of the bid.

Each Surety executing this instrument agrees that its obligation is not impaired by any extension(s) of the time for acceptance of the bid that the Principal may grant to the Government. Notice to the surety(ies) of extension(s) is waived. However, waiver of the notice applies only to extensions aggregating not more than sixty (60) calendar days in addition to the period originally allowed for acceptance of the bid.

WITNESS:

The Principal and Surety(ies) executed this bid bond and affixed their seals on the above date.

PRINCIPAL

SIGNATURE(S)	1. (Seal)	2. (Seal)	3. (Seal)	Corporate Seal
NAME(S) & TITLE(S) *(Typed)*	1.	2.	3.	

INDIVIDUAL SURETY(IES)

SIGNATURE(S)	1. (Seal)	2. (Seal)
NAME(S) *(Typed)*	1.	2.

CORPORATE SURETY(IES)

SURETY A	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 24 (REV. DATE)
Prescribed by GSA - FAR (48 CFR) 53.228(a)

SURETY B	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY C	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY D	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY E	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY F	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY G	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

INSTRUCTIONS

1. This form is authorized for use when a bid guaranty is required. Any deviation from this form will require the written approval of the Administrator of General Services.

2. Insert the full legal name and business address of the Principal in the space designated "Principal" on the face of the form. An authorized person shall sign the bond. Any person signing in a representative capacity (e.g., an attorney-in-fact) must furnish evidence of authority if that representative is not a member of the firm, partnership, or joint venture, or an officer of the corporation involved.

3. The bond may express penal sum as a percentage of the bid price. In these cases, the bond may state a maximum dollar limitation (e.g., 20% of the bid price but the amount not to exceed ____________ dollars).

4. (a) Corporations executing the bond as sureties must appear on the Department of the Treasury's list of approved sureties and must act within the limitations listed therein. The value put into the LIABILITY LIMIT block is the penal sum (i.e., the face value) of the bond, unless a co-surety arrangement is proposed.

(b) When multiple corporate sureties are involved, their names and addresses shall appear in the spaces (Surety A, Surety B, etc.) headed "CORPORATE SURETY(IES)." In the space designated "SURETY(IES)" on the face of the form, insert only the letter identifier corresponding to each of the sureties. Moreover, when co-surety arrangements exist, the parties may allocate their respective limitations of liability under the bond, provided that the sum total of their liability equals 100% of the bond penal sum.

(c) When individual sureties are involved, a completed Affidavit of Individual Surety (Standard Form 28) for each individual surety, shall accompany the bond. The Government may require the surety to furnish additional substantiating information concerning its financial capability.

5. Corporations executing the bond shall affix their corporate seals. Individuals shall execute the bond opposite the word "Corporate Seal"; and shall affix an adhesive seal if executed in Maine, New Hampshire, or any other jurisdiction requiring adhesive seals.

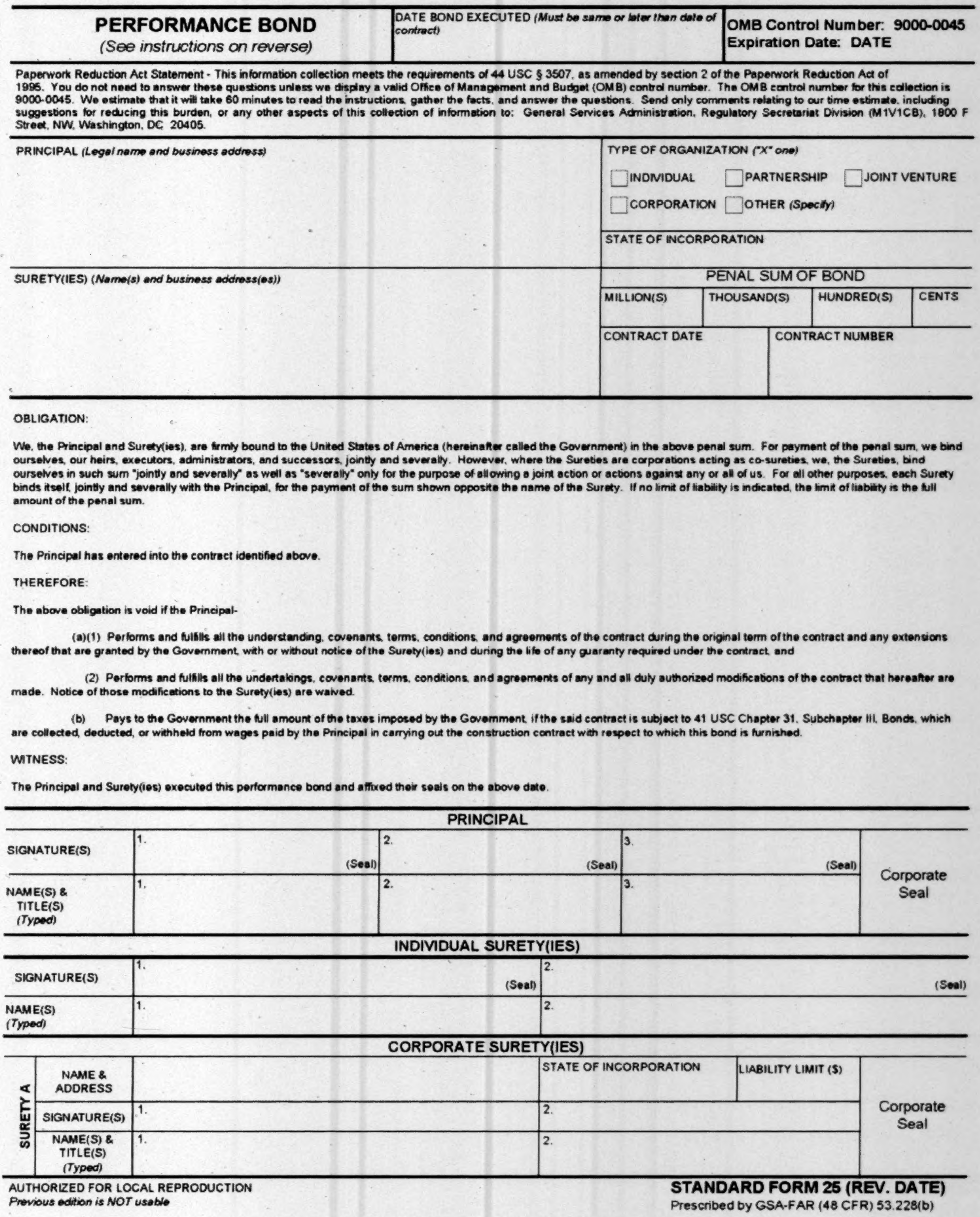
6. Type the name and title of each person signing this bond in the space provided.

7. In its application to negotiated contracts, the terms "bid" and "bidder" shall include "proposal" and "offeror."

STANDARD FORM 24 (REV. DATE) **BACK**

■ 4. Revise section 53.301–25 to read as follows:

53.301–25 Performance Bond.



PERFORMANCE BOND
(See instructions on reverse)

DATE BOND EXECUTED *(Must be same or later than date of contract)*

OMB Control Number: 9000-0045
Expiration Date: DATE

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 USC § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0045. We estimate that it will take 60 minutes to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

PRINCIPAL *(Legal name and business address)*

TYPE OF ORGANIZATION *("X" one)*
☐ INDIVIDUAL ☐ PARTNERSHIP ☐ JOINT VENTURE
☐ CORPORATION ☐ OTHER *(Specify)*

STATE OF INCORPORATION

SURETY(IES) *(Name(s) and business address(es))*

PENAL SUM OF BOND

MILLION(S)	THOUSAND(S)	HUNDRED(S)	CENTS

CONTRACT DATE	CONTRACT NUMBER

OBLIGATION:

We, the Principal and Surety(ies), are firmly bound to the United States of America (hereinafter called the Government) in the above penal sum. For payment of the penal sum, we bind ourselves, our heirs, executors, administrators, and successors, jointly and severally. However, where the Sureties are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum "jointly and severally" as well as "severally" only for the purpose of allowing a joint action or actions against any or all of us. For all other purposes, each Surety binds itself, jointly and severally with the Principal, for the payment of the sum shown opposite the name of the Surety. If no limit of liability is indicated, the limit of liability is the full amount of the penal sum.

CONDITIONS:

The Principal has entered into the contract identified above.

THEREFORE:

The above obligation is void if the Principal-

(a)(1) Performs and fulfills all the understanding, covenants, terms, conditions, and agreements of the contract during the original term of the contract and any extensions thereof that are granted by the Government, with or without notice of the Surety(ies) and during the life of any guaranty required under the contract, and

(2) Performs and fulfills all the undertakings, covenants, terms, conditions, and agreements of any and all duly authorized modifications of the contract that hereafter are made. Notice of those modifications to the Surety(ies) are waived.

(b) Pays to the Government the full amount of the taxes imposed by the Government, if the said contract is subject to 41 USC Chapter 31, Subchapter III, Bonds, which are collected, deducted, or withheld from wages paid by the Principal in carrying out the construction contract with respect to which this bond is furnished.

WITNESS:

The Principal and Surety(ies) executed this performance bond and affixed their seals on the above date.

PRINCIPAL

SIGNATURE(S)	1. (Seal)	2. (Seal)	3. (Seal)	Corporate Seal
NAME(S) & TITLE(S) *(Typed)*	1.	2.	3.	

INDIVIDUAL SURETY(IES)

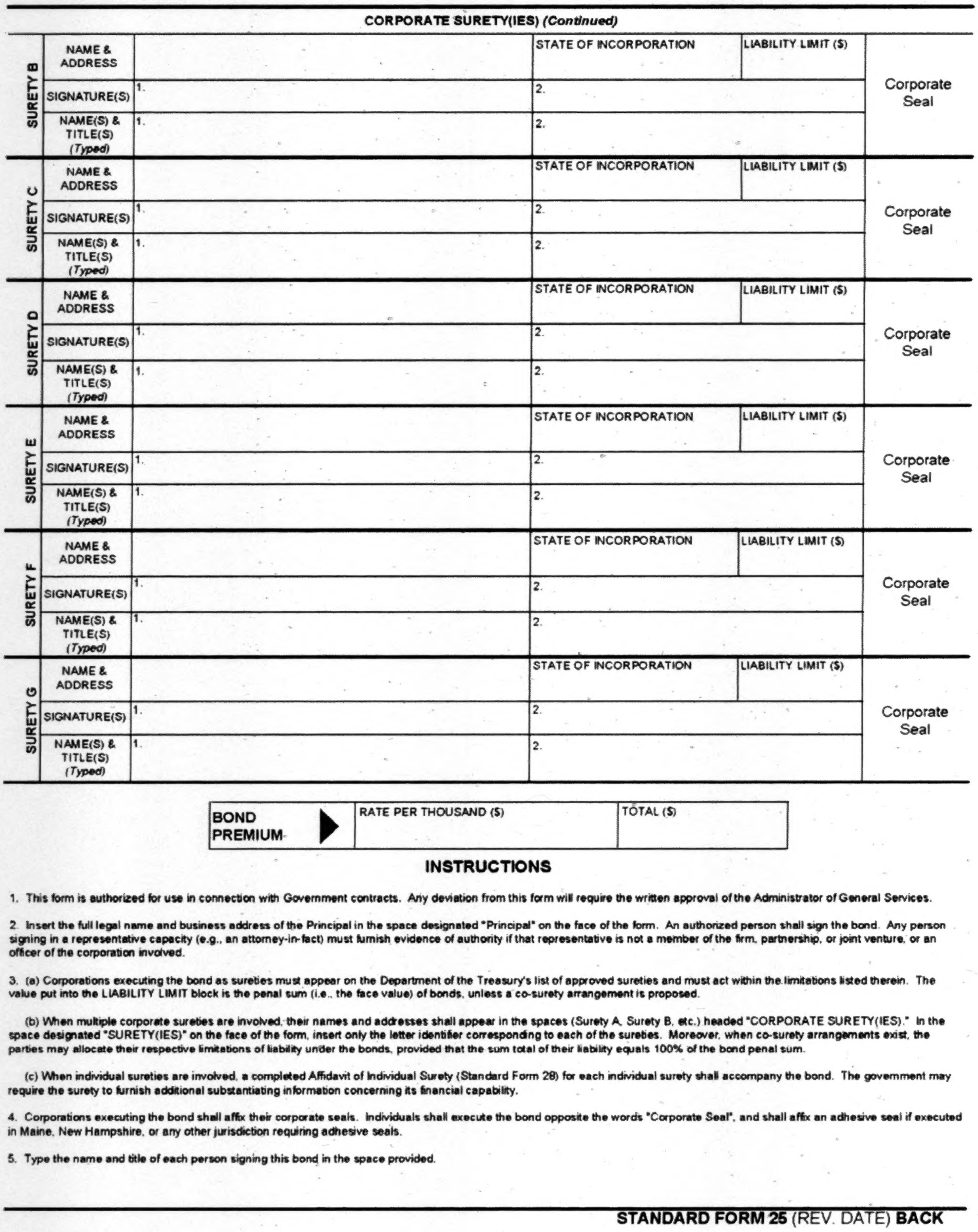
SIGNATURE(S)	1. (Seal)	2. (Seal)
NAME(S) *(Typed)*	1.	2.

CORPORATE SURETY(IES)

SURETY A	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 25 (REV. DATE)
Prescribed by GSA-FAR (48 CFR) 53.228(b)



CORPORATE SURETY(IES) ***(Continued)***

SURETY B	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY C	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY D	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY E	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY F	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY G	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT ($)	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

BOND PREMIUM ▶	RATE PER THOUSAND ($)	TOTAL ($)

INSTRUCTIONS

1. This form is authorized for use in connection with Government contracts. Any deviation from this form will require the written approval of the Administrator of General Services.

2. Insert the full legal name and business address of the Principal in the space designated "Principal" on the face of the form. An authorized person shall sign the bond. Any person signing in a representative capacity (e.g., an attorney-in-fact) must furnish evidence of authority if that representative is not a member of the firm, partnership, or joint venture, or an officer of the corporation involved.

3. (a) Corporations executing the bond as sureties must appear on the Department of the Treasury's list of approved sureties and must act within the limitations listed therein. The value put into the LIABILITY LIMIT block is the penal sum (i.e., the face value) of bonds, unless a co-surety arrangement is proposed.

(b) When multiple corporate sureties are involved, their names and addresses shall appear in the spaces (Surety A, Surety B, etc.) headed "CORPORATE SURETY(IES)." In the space designated "SURETY(IES)" on the face of the form, insert only the letter identifier corresponding to each of the sureties. Moreover, when co-surety arrangements exist, the parties may allocate their respective limitations of liability under the bonds, provided that the sum total of their liability equals 100% of the bond penal sum.

(c) When individual sureties are involved, a completed Affidavit of Individual Surety (Standard Form 28) for each individual surety shall accompany the bond. The government may require the surety to furnish additional substantiating information concerning its financial capability.

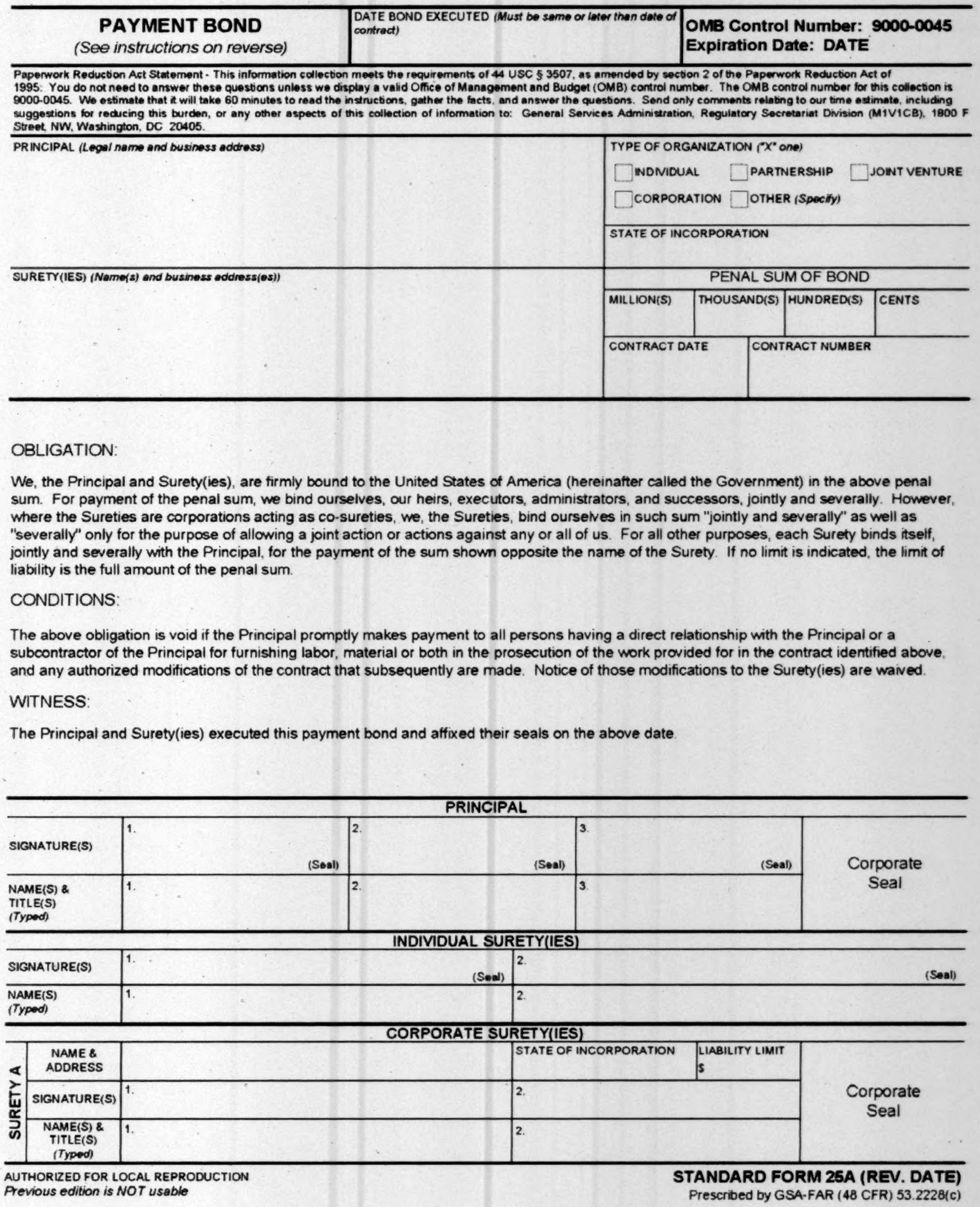
4. Corporations executing the bond shall affix their corporate seals. Individuals shall execute the bond opposite the words "Corporate Seal", and shall affix an adhesive seal if executed in Maine, New Hampshire, or any other jurisdiction requiring adhesive seals.

5. Type the name and title of each person signing this bond in the space provided.

STANDARD FORM 25 (REV. DATE) **BACK**

■ 5. Revise section 53.301–25A to read as follows:

53.301–25A Payment Bond.



PAYMENT BOND *(See instructions on reverse)*	DATE BOND EXECUTED *(Must be same or later than date of contract)*	**OMB Control Number: 9000-0045** **Expiration Date: DATE**

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 USC § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0045. We estimate that it will take 60 minutes to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

PRINCIPAL *(Legal name and business address)*

TYPE OF ORGANIZATION *("X" one)*

☐ INDIVIDUAL ☐ PARTNERSHIP ☐ JOINT VENTURE

☐ CORPORATION ☐ OTHER *(Specify)*

STATE OF INCORPORATION

SURETY(IES) *(Name(s) and business address(es))*

PENAL SUM OF BOND

MILLION(S)	THOUSAND(S)	HUNDRED(S)	CENTS

CONTRACT DATE	CONTRACT NUMBER

OBLIGATION:

We, the Principal and Surety(ies), are firmly bound to the United States of America (hereinafter called the Government) in the above penal sum. For payment of the penal sum, we bind ourselves, our heirs, executors, administrators, and successors, jointly and severally. However, where the Sureties are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum "jointly and severally" as well as "severally" only for the purpose of allowing a joint action or actions against any or all of us. For all other purposes, each Surety binds itself, jointly and severally with the Principal, for the payment of the sum shown opposite the name of the Surety. If no limit is indicated, the limit of liability is the full amount of the penal sum.

CONDITIONS:

The above obligation is void if the Principal promptly makes payment to all persons having a direct relationship with the Principal or a subcontractor of the Principal for furnishing labor, material or both in the prosecution of the work provided for in the contract identified above, and any authorized modifications of the contract that subsequently are made. Notice of those modifications to the Surety(ies) are waived.

WITNESS:

The Principal and Surety(ies) executed this payment bond and affixed their seals on the above date.

PRINCIPAL

SIGNATURE(S)	1. (Seal)	2. (Seal)	3. (Seal)	Corporate Seal
NAME(S) & TITLE(S) *(Typed)*	1.	2.	3.	

INDIVIDUAL SURETY(IES)

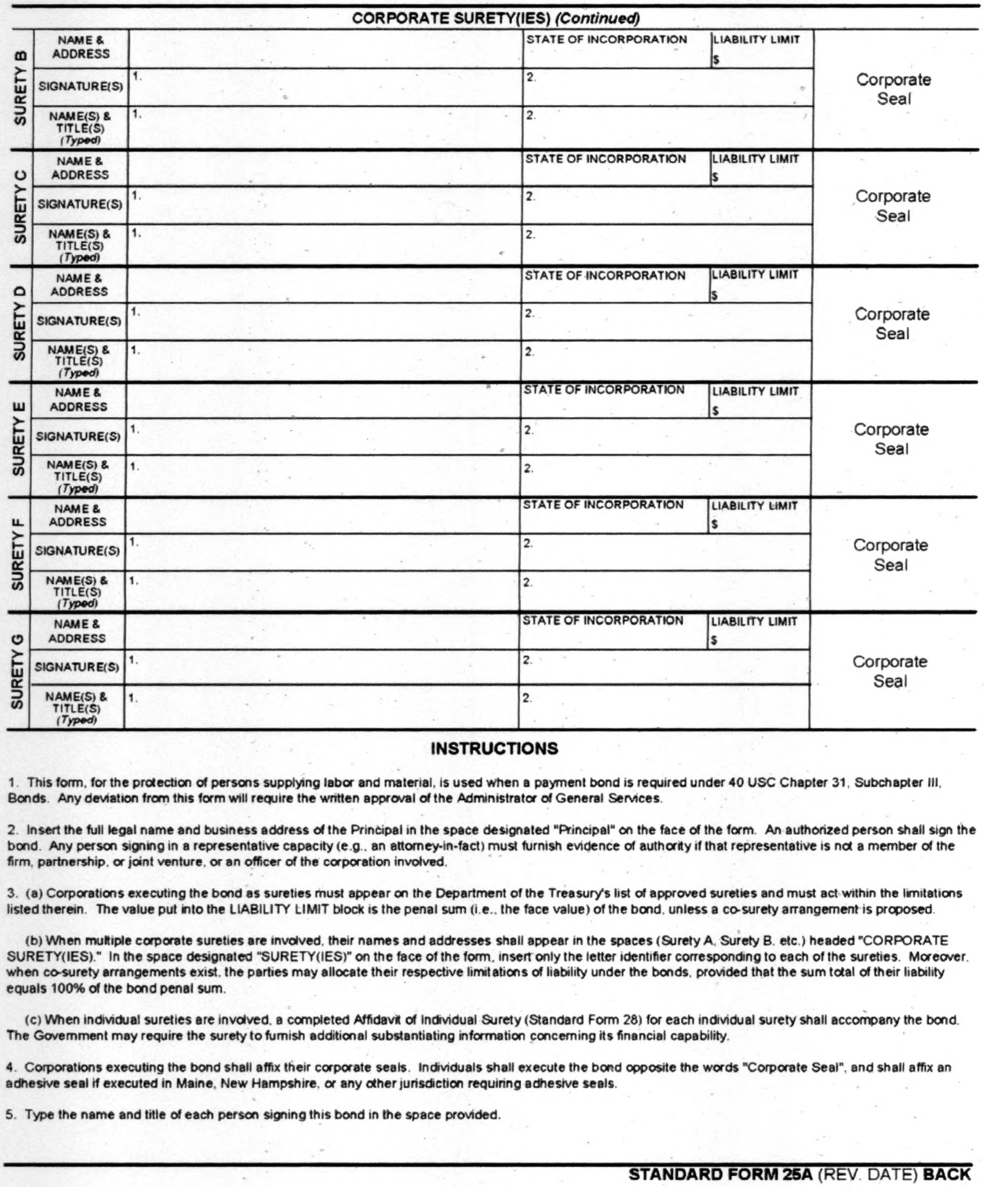
SIGNATURE(S)	1. (Seal)	2. (Seal)
NAME(S) *(Typed)*	1.	2.

CORPORATE SURETY(IES)

SURETY A	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 25A (REV. DATE)
Prescribed by GSA-FAR (48 CFR) 53.2228(c)



CORPORATE SURETY(IES) ***(Continued)***

SURETY B	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY C	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY D	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY E	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY F	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		
SURETY G	NAME & ADDRESS		STATE OF INCORPORATION	LIABILITY LIMIT $	Corporate Seal
	SIGNATURE(S)	1.	2.		
	NAME(S) & TITLE(S) *(Typed)*	1.	2.		

INSTRUCTIONS

1. This form, for the protection of persons supplying labor and material, is used when a payment bond is required under 40 USC Chapter 31, Subchapter III, Bonds. Any deviation from this form will require the written approval of the Administrator of General Services.

2. Insert the full legal name and business address of the Principal in the space designated "Principal" on the face of the form. An authorized person shall sign the bond. Any person signing in a representative capacity (e.g., an attorney-in-fact) must furnish evidence of authority if that representative is not a member of the firm, partnership, or joint venture, or an officer of the corporation involved.

3. (a) Corporations executing the bond as sureties must appear on the Department of the Treasury's list of approved sureties and must act within the limitations listed therein. The value put into the LIABILITY LIMIT block is the penal sum (i.e., the face value) of the bond, unless a co-surety arrangement is proposed.

(b) When multiple corporate sureties are involved, their names and addresses shall appear in the spaces (Surety A, Surety B, etc.) headed "CORPORATE SURETY(IES)." In the space designated "SURETY(IES)" on the face of the form, insert only the letter identifier corresponding to each of the sureties. Moreover, when co-surety arrangements exist, the parties may allocate their respective limitations of liability under the bonds, provided that the sum total of their liability equals 100% of the bond penal sum.

(c) When individual sureties are involved, a completed Affidavit of Individual Surety (Standard Form 28) for each individual surety shall accompany the bond. The Government may require the surety to furnish additional substantiating information concerning its financial capability.

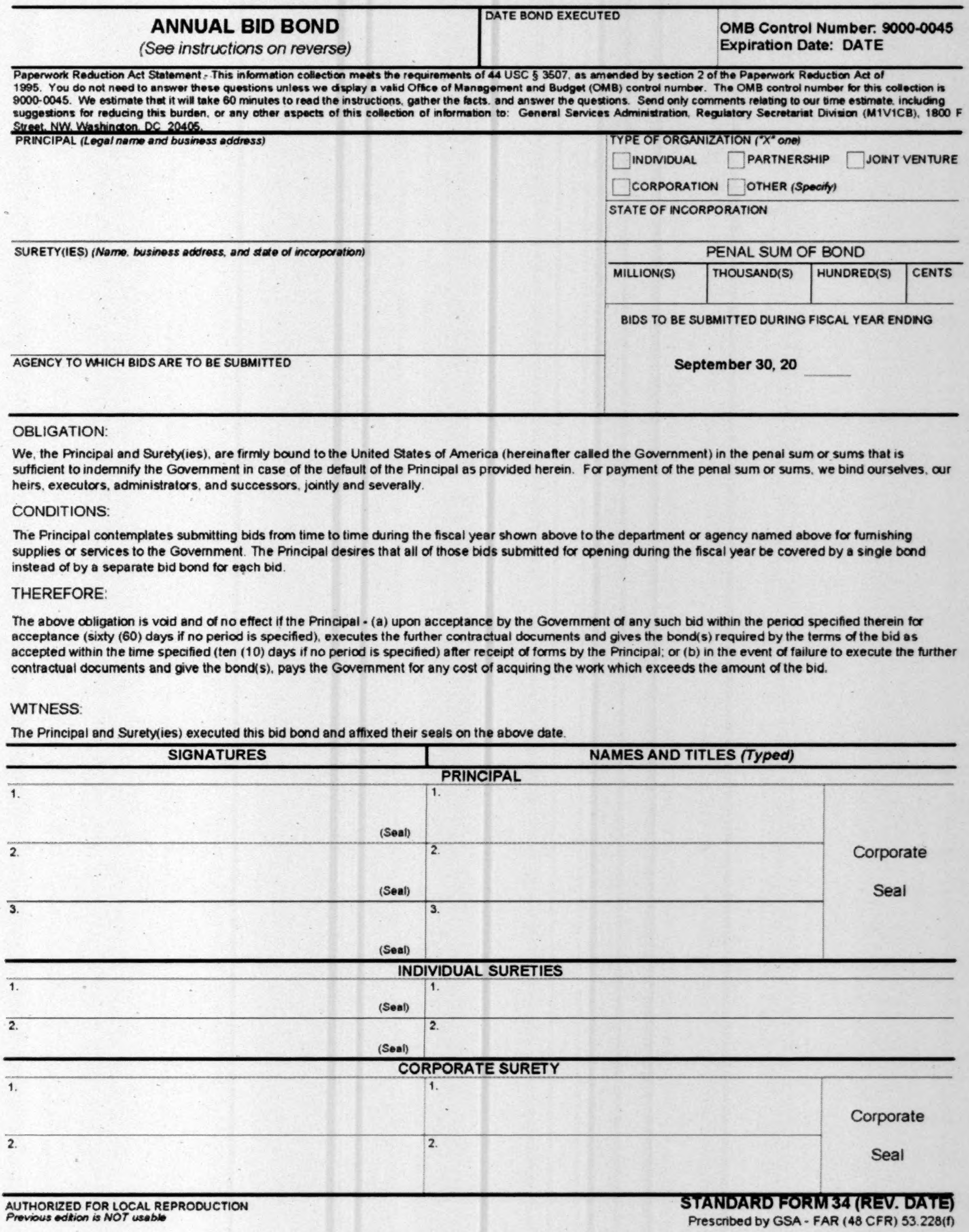
4. Corporations executing the bond shall affix their corporate seals. Individuals shall execute the bond opposite the words "Corporate Seal", and shall affix an adhesive seal if executed in Maine, New Hampshire, or any other jurisdiction requiring adhesive seals.

5. Type the name and title of each person signing this bond in the space provided.

STANDARD FORM 25A (REV. DATE) **BACK**

■ 6. Revise section 53.301–34 to read as follows:

53.301–34 Annual Bid Bond.



ANNUAL BID BOND

(See instructions on reverse)

DATE BOND EXECUTED

OMB Control Number: 9000-0045
Expiration Date: DATE

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 USC § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0045. We estimate that it will take 60 minutes to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

PRINCIPAL *(Legal name and business address)*

TYPE OF ORGANIZATION *("X" one)*
☐ INDIVIDUAL ☐ PARTNERSHIP ☐ JOINT VENTURE
☐ CORPORATION ☐ OTHER *(Specify)*

STATE OF INCORPORATION

SURETY(IES) *(Name, business address, and state of incorporation)*

PENAL SUM OF BOND

MILLION(S)	THOUSAND(S)	HUNDRED(S)	CENTS

AGENCY TO WHICH BIDS ARE TO BE SUBMITTED

BIDS TO BE SUBMITTED DURING FISCAL YEAR ENDING

September 30, 20 ____

OBLIGATION:

We, the Principal and Surety(ies), are firmly bound to the United States of America (hereinafter called the Government) in the penal sum or sums that is sufficient to indemnify the Government in case of the default of the Principal as provided herein. For payment of the penal sum or sums, we bind ourselves, our heirs, executors, administrators, and successors, jointly and severally.

CONDITIONS:

The Principal contemplates submitting bids from time to time during the fiscal year shown above to the department or agency named above for furnishing supplies or services to the Government. The Principal desires that all of those bids submitted for opening during the fiscal year be covered by a single bond instead of by a separate bid bond for each bid.

THEREFORE:

The above obligation is void and of no effect if the Principal - (a) upon acceptance by the Government of any such bid within the period specified therein for acceptance (sixty (60) days if no period is specified), executes the further contractual documents and gives the bond(s) required by the terms of the bid as accepted within the time specified (ten (10) days if no period is specified) after receipt of forms by the Principal; or (b) in the event of failure to execute the further contractual documents and give the bond(s), pays the Government for any cost of acquiring the work which exceeds the amount of the bid.

WITNESS:

The Principal and Surety(ies) executed this bid bond and affixed their seals on the above date.

SIGNATURES	**NAMES AND TITLES *(Typed)***	
	PRINCIPAL	
1. (Seal)	1.	Corporate Seal
2. (Seal)	2.	
3. (Seal)	3.	
	INDIVIDUAL SURETIES	
1. (Seal)	1.	
2. (Seal)	2.	
	CORPORATE SURETY	
1.	1.	Corporate Seal
2.	2.	

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 34 (REV. DATE)
Prescribed by GSA - FAR (48 CFR) 53.228(f)

INSTRUCTIONS

1. This form is authorized for use in the acquisition of supplies and services, excluding construction, in lieu of Standard Form 24 (Bid Bond). Any deviation from this form will require the written approval of the Administrator of General Services.

2. Insert the full legal name and business address of the Principal in the space designated "Principal" on the face of the form. An authorized person shall sign the bond. Any person signing in a representative capacity (e.g., an attorney-in-fact) must furnish evidence of authority if that representative is not a member of the firm, partnership, or joint venture, or an officer of the corporation involved.

3. (a) Corporations executing the bond as sureties must appear on the Department of the Treasury's list of approved sureties and must act within the limitations listed therein.

(b) When individual sureties are involved, a completed Affidavit of Individual Surety (Standard Form 28) for each individual surety shall accompany the bond. The Government may require the surety to furnish additional substantiating information concerning its financial capability.

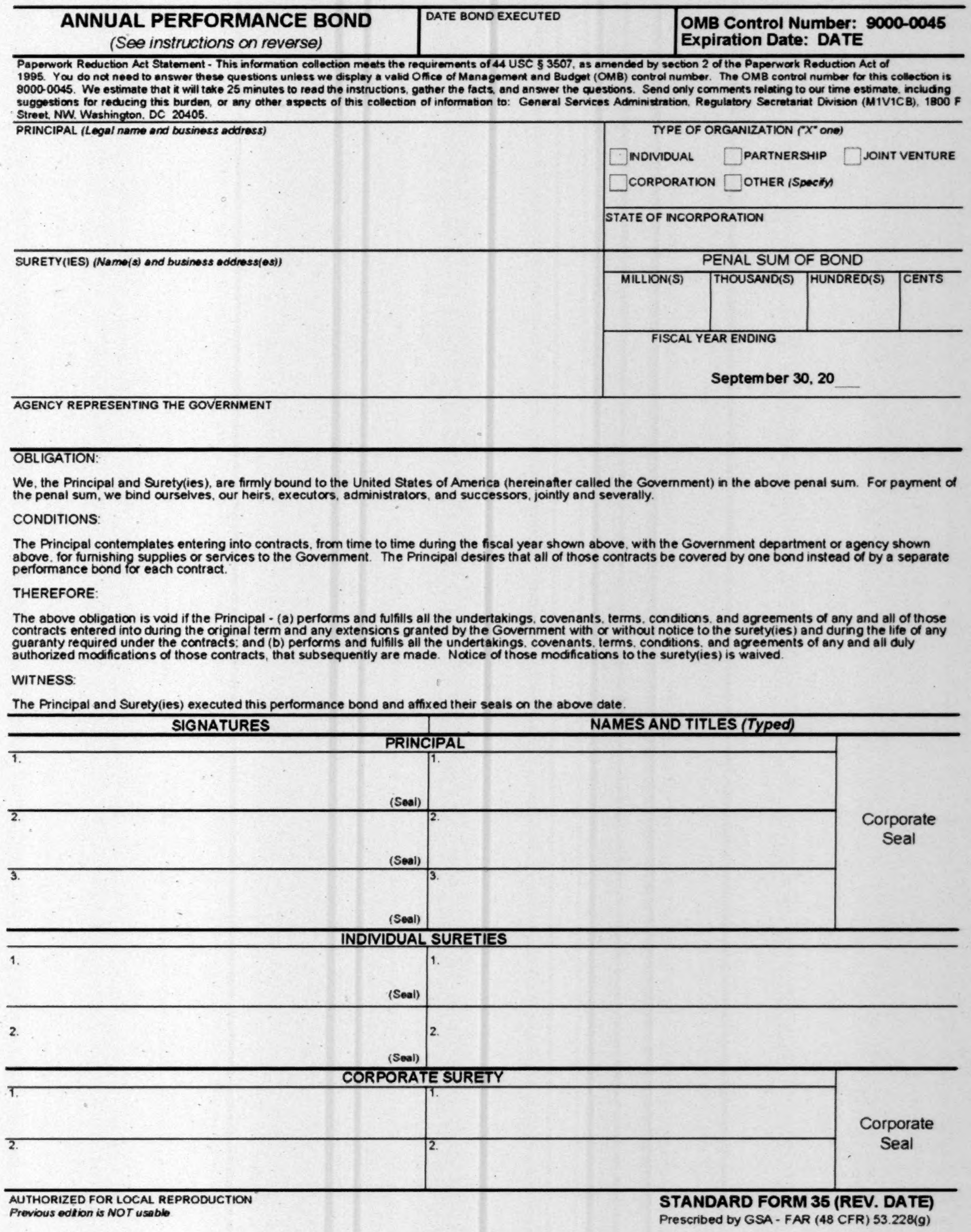
4. Corporations executing the bond shall affix their corporate seals. Individuals shall execute the bond opposite the word "Corporate Seal", and shall affix an adhesive seal if executed in Maine, New Hampshire, or any other jurisdiction requiring adhesive seals.

5. Type the name and title of each person signing this bond in the space provided.

6. In its application to negotiated contracts, the terms "bid" and "bidder" shall include "proposal" and "offeror."

■ 7. Revise section 53.301–35 to read as follows:

53.301–35 Annual Performance Bond.



ANNUAL PERFORMANCE BOND *(See instructions on reverse)*	DATE BOND EXECUTED	**OMB Control Number: 9000-0045** **Expiration Date: DATE**

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 USC § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget (OMB) control number. The OMB control number for this collection is 9000-0045. We estimate that it will take 25 minutes to read the instructions, gather the facts, and answer the questions. Send only comments relating to our time estimate, including suggestions for reducing this burden, or any other aspects of this collection of information to: General Services Administration, Regulatory Secretariat Division (M1V1CB), 1800 F Street, NW, Washington, DC 20405.

PRINCIPAL *(Legal name and business address)*

TYPE OF ORGANIZATION *("X" one)*

☐ INDIVIDUAL ☐ PARTNERSHIP ☐ JOINT VENTURE

☐ CORPORATION ☐ OTHER *(Specify)*

STATE OF INCORPORATION

SURETY(IES) *(Name(s) and business address(es))*

PENAL SUM OF BOND

MILLION(S)	THOUSAND(S)	HUNDRED(S)	CENTS

FISCAL YEAR ENDING

September 30, 20___

AGENCY REPRESENTING THE GOVERNMENT

OBLIGATION:

We, the Principal and Surety(ies), are firmly bound to the United States of America (hereinafter called the Government) in the above penal sum. For payment of the penal sum, we bind ourselves, our heirs, executors, administrators, and successors, jointly and severally.

CONDITIONS:

The Principal contemplates entering into contracts, from time to time during the fiscal year shown above, with the Government department or agency shown above, for furnishing supplies or services to the Government. The Principal desires that all of those contracts be covered by one bond instead of by a separate performance bond for each contract.

THEREFORE:

The above obligation is void if the Principal - (a) performs and fulfills all the undertakings, covenants, terms, conditions, and agreements of any and all of those contracts entered into during the original term and any extensions granted by the Government with or without notice to the surety(ies) and during the life of any guaranty required under the contracts; and (b) performs and fulfills all the undertakings, covenants, terms, conditions, and agreements of any and all duly authorized modifications of those contracts, that subsequently are made. Notice of those modifications to the surety(ies) is waived.

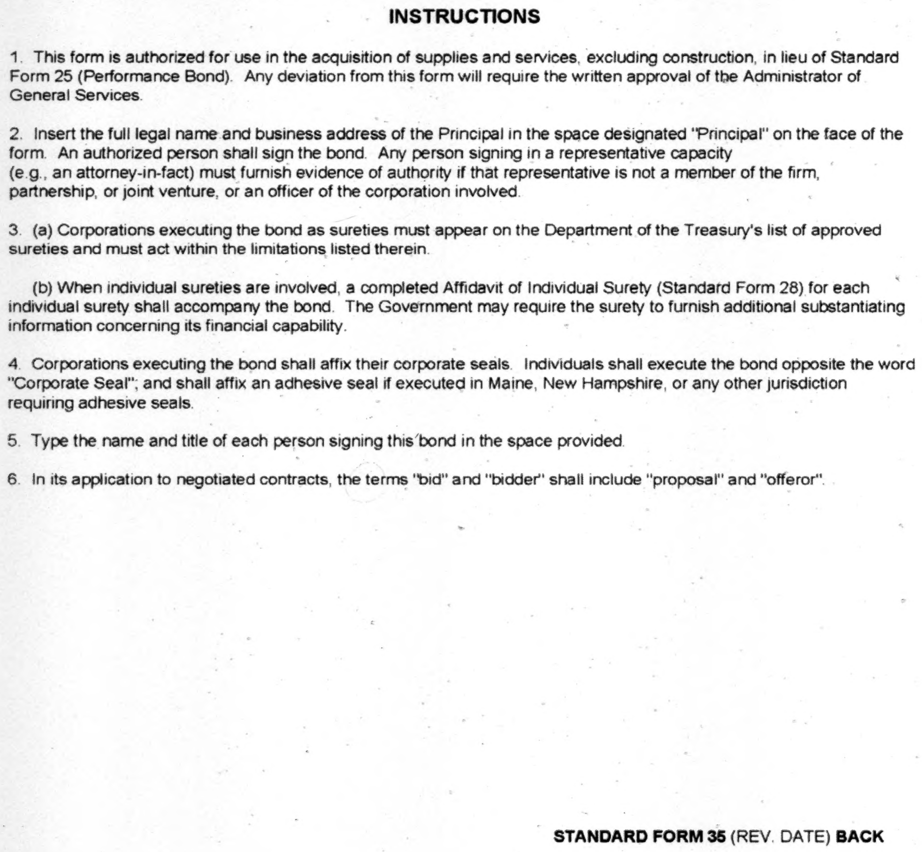
WITNESS:

The Principal and Surety(ies) executed this performance bond and affixed their seals on the above date.

SIGNATURES	NAMES AND TITLES *(Typed)*	
PRINCIPAL		
1. (Seal)	1.	Corporate Seal
2. (Seal)	2.	
3. (Seal)	3.	
INDIVIDUAL SURETIES		
1. (Seal)	1.	
2. (Seal)	2.	
CORPORATE SURETY		
1.	1.	Corporate Seal
2.	2.	

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 35 (REV. DATE)
Prescribed by GSA - FAR (48 CFR) 53.228(g)



INSTRUCTIONS

1. This form is authorized for use in the acquisition of supplies and services, excluding construction, in lieu of Standard Form 25 (Performance Bond). Any deviation from this form will require the written approval of the Administrator of General Services.

2. Insert the full legal name and business address of the Principal in the space designated "Principal" on the face of the form. An authorized person shall sign the bond. Any person signing in a representative capacity (e.g., an attorney-in-fact) must furnish evidence of authority if that representative is not a member of the firm, partnership, or joint venture, or an officer of the corporation involved.

3. (a) Corporations executing the bond as sureties must appear on the Department of the Treasury's list of approved sureties and must act within the limitations listed therein.

(b) When individual sureties are involved, a completed Affidavit of Individual Surety (Standard Form 28) for each individual surety shall accompany the bond. The Government may require the surety to furnish additional substantiating information concerning its financial capability.

4. Corporations executing the bond shall affix their corporate seals. Individuals shall execute the bond opposite the word "Corporate Seal"; and shall affix an adhesive seal if executed in Maine, New Hampshire, or any other jurisdiction requiring adhesive seals.

5. Type the name and title of each person signing this bond in the space provided.

6. In its application to negotiated contracts, the terms "bid" and "bidder" shall include "proposal" and "offeror".

STANDARD FORM 35 (REV. DATE) **BACK**

[FR Doc. 2016–16248 Filed 7–13–16; 8:45 a.m.]

BILLING CODE 6820–14–C

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4 and 52

[FAC 2005–89; Item V; Docket No. 2016–0052; Sequence No. 3]

Federal Acquisition Regulation; Technical Amendments

AGENCY: Department of Defense (DoD), General Services Administration (GSA),

FOR FURTHER INFORMATION CONTACT: Ms. Hada Flowers, Regulatory Secretariat Division (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405, 202–501–4755. Please cite FAC 2005–89, Technical Amendments.

SUPPLEMENTARY INFORMATION: In order to update certain elements in 48 CFR parts 4 and 52 this document makes editorial changes to the FAR.

List of Subjects in 48 CFR Parts 4 and 52

Government procurement.

Dated: June 30, 2016.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

PART 4—ADMINISTRATIVE MATTERS

■ 2. Amend section 4.1801 by revising the definition of "Commercial and Government Entity (CAGE) code" to read as follows:

4.1801 Definitions.

* * * * *

Commercial and Government Entity (CAGE) code means–

(1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity; or

(2) An identifier assigned by a member of the North Atlantic Treaty

■ 3. Amend section 4.1803 by revising paragraph (b) to read as follows:

4.1803 Verifying CAGE codes prior to award.

* * * * *

(b) For entities not required to be registered in SAM, the contracting officer shall validate the CAGE code using the CAGE code search feature at *https://cage.dla.mil.*

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 52.204–16 by—
■ a. Revising the date of the provision;
■ b. In paragraph (a), revising the definition of "Commercial and Government Entity (CAGE) code";
■ c. Removing from paragraph (c)(1) the word "Contractor" and adding "Commercial" in its place; and
■ d. Revising paragraphs (c)(2) and (3), and (d).

The revisions read as follows:

52.204–16 Commercial and Government Entity Code Reporting.

* * * * *

Commercial and Government Entity Code Reporting (Jul 2016)

* * * * *

Commercial and Government Entity (CAGE) code means—

(1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity; or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by the NATO Support and Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

(c) * * *

(2) The DLA Commercial and Government Entity (CAGE) Branch. If registration in SAM is not required for the subject procurement, and the offeror does not otherwise register in SAM, an offeror located in the United States or its outlying areas may request that a CAGE code be assigned by submitting a request at *https://cage.dla.mil.*

(3) The appropriate country codification bureau. Entities located outside the United States and its outlying areas may obtain an additional information on obtaining NCAGE codes, are available at *http://www.nato.int/structur/AC/135/main/links/contacts.htm.*

(d) Additional guidance for establishing and maintaining CAGE codes is available at *https://cage.dla.mil.*

* * * * *

■ 5. Amend section 52.204–17 by—
■ a. Revising the date of the provision; and
■ b. In paragraph (a), revising the definition of "Commercial and Government Entity (CAGE) code".

The revisions read as follows:

52.204–17 Ownership or Control of Offeror.

* * * * *

Ownership or Control of Offeror (Jul 2016)

* * * * *

Commercial and Government Entity (CAGE) code means—

(1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity; or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by the NATO Support and Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

* * * * *

■ 6. Amend section 52.204–18 by—
■ a. Revising the date of the clause;
■ b. In paragraph (a), revising the definition of "Commercial and Government Entity (CAGE) code";
■ c. Removing from paragraph (b) the word "DLA Contractor" and adding "DLA Commercial" in its place; and
■ d. Revising paragraphs (c) through (e);

The revisions read as follows:

52.204–18 Commercial and Government Entity Code Maintenance.

* * * * *

Commercial and Government Entity Code Maintenance (Jul 2016)

* * * * *

Commercial and Government Entity (CAGE) code means— Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

* * * * *

(c) Contractors located in the United States or its outlying areas that are not registered in SAM shall submit written change requests to the DLA Commercial and Government Entity (CAGE) Branch. Requests for changes shall be provided at *https://cage.dla.mil.* Change requests to the CAGE master file are accepted from the entity identified by the code.

(d) Contractors located outside the United States and its outlying areas that are not registered in SAM shall contact the appropriate National Codification Bureau (points of contact available at *http://www.nato.int/structur/AC/135/main/links/contacts.htm*) or NSPA at *https://eportal.nspa.nato.int/AC135Public/scage/CageList.aspx* to request CAGE changes.

(e) Additional guidance for maintaining CAGE codes is available at *https://cage.dla.mil.*

■ 7. Amend section 52.204–20 by—
■ a. Revising the date of the provision; and
■ b. In paragraph (a), revising the definition "Commercial and Government Entity (CAGE) code".

The revisions read as follows:

52.204–20 Predecessor of Offeror.

* * * * *

Predecessor of Offeror (Jul 2016)

* * * * *

Commercial and Government Entity (CAGE) code means—

(1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity; or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by the NATO Support and Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

* * * * *

■ 8. Amend section 52.212–3 by revising the date of the provision, and removing from the introductory text

Offeror Representations and Certifications—Commercial Items (Jul 2016)

* * * * *

[FR Doc. 2016–16249 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2016–0051, Sequence No. 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–89; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rules appearing in Federal Acquisition Circular (FAC) 2005–89, which amends the Federal Acquisition Regulation (FAR). An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared. Interested parties may obtain further information regarding these rules by referring to FAC 2005–89, which precedes this document. These documents are also available via the Internet at *http://www.regulations.gov.*

DATES: July 14, 2016.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2005–89 and the FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2005–89

Item	Subject	FAR Case	Analyst
*I	Small Business Subcontracting Improvements	2014–003	Uddowla.
II	OMB Circular Citation Update	2014–023	Hopkins.
III	FPI Blanket Waiver Threshold	2016–008	Uddowla.
*IV	Revision to Standard Forms for Bonds	2015–025	Hopkins.
V	Technical Amendments		

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–89 amends the FAR as follows:

Item I—Small Business Subcontracting Improvements (FAR Case 2014–003)

This final rule amends the FAR to implement SBA's final rule published at 78 FR 42391 on July 16, 2013. The rule will implement the statutory requirements set forth in section 1321 and 1322 of the Small Business Jobs Act of 2010, (Pub. L. 111–240), as well as other requirements aimed at improving subcontracting regulations to increase small business opportunities. This rule accomplishes the following:

(1) Requires prime contractors to make good faith efforts to utilize their proposed small business subcontractors during performance of a contract to the same degree the prime contractor relied on the small business in preparing and submitting its bid or proposal. To the extent a prime contractor is unable to make a good faith effort to utilize its small business subcontractors as described above, the prime contractor is required to explain, in writing, within 30 days of contract completion, to the contracting officer the reasons why it was unable to do so.

(2) Authorizes contracting officers to calculate subcontracting goals in terms of total contract dollars in addition to the required goals in terms of total subcontracted dollars.

(3) Provides contracting officers with the discretion to require a subcontracting plan in instances where a small business rerepresents its size as an other than small business.

(4) Requires subcontracting plans even for modifications under the subcontracting plan threshold if said modifications would cause the contract to exceed the plan threshold.

(5) Requires prime contractors to assign North American Industry Classification System (NAICS) codes to subcontracts.

(6) Restricts prime contractors from prohibiting a subcontractor from discussing payment or utilization matters with the contracting officer.

(7) Requires prime contractors to resubmit a corrected subcontracting report within 30 days of receiving the contracting officer's notice of report rejection.

(8) Requires prime contractors to provide the socioeconomic status of the subcontractor in the notification to unsuccessful offerors for subcontracts.

(9) Requires prime contracts with subcontracting plans on task and delivery order contracts to report order level subcontracting information after November 2017.

(10) Facilitates funding agencies receiving small business subcontracting credit.

(11) On indefinite-delivery, indefinite-quantity contracts, allows the contracting officer to establish subcontracting goals at the order level (but not a new subcontracting plan).

This rule may have a positive economic impact on any small business entity that wishes to participate in the Federal procurement arena as a subcontractor.

Item II—OMB Circular Citation Update (FAR Case 2014–023)

This final rule amends the FAR to update outdated OMB Circular citation references. On December 26, 2013, the Office of Management and Budget (OMB) published new guidance at 2

CFR part 200 entitled Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, adopted by Federal agencies as a set of binding regulations that became effective December 26, 2014. This new guidance supersedes and streamlines requirements from OMB Circulars A–21, A–87, A–89, A–102, A–110, A–122, and A–133, as well as the guidance in Circular A–50 on Audit Followup. As such, this final rule replaces OMB citations in the FAR to the circulars cited above that have been superseded. The replacement of these outdated OMB citations in the FAR will have no impact on small businesses since the intent of the OMB guidance remains unchanged.

Item III—FPI Blanket Waiver Threshold (FAR Case 2016–008)

This final rule amends the FAR to increase the blanket waiver threshold for small dollar-value purchases from Federal Prison Industries (FPI) by Federal agencies from $3,000 to $3,500. No waiver is required to buy from an alternative source below $3,500. Customers may, however, still purchase from FPI at, or below, this threshold, if they so choose.

Item IV—Revision to Standard Forms for Bonds (FAR Case 2015–025)

This rule amends the FAR to revise five Standard Forms prescribed for contracts involving bonds and other financial protections. The revisions, aimed at clarifying liability limitations and expanding the options for organization types, are made to Standard Forms 24, 25, 25A, 34, and 35. These changes will minimize questions from industry to the contracting officer.

This final rule does not place any new requirements on small entities.

Item V—Technical Amendments

Editorial changes are made at FAR 4.1801, 4.1803, 52.204–16, 52.204–17, 52.204–18, 52.204–20, and 52.212–3.

Dated: June 30, 2016.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2016–16250 Filed 7–13–16; 8:45 am]

BILLING CODE 6820–EP–P

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 139
Safety Management System for Certificated Airports; Proposed Rules

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 139

[Docket No.: FAA–2010–0997; Notice No. 16–04]

RIN 2120–AJ38

Safety Management System for Certificated Airports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: On October 7, 2010, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to require certificate holders to establish a safety management system (SMS) for the entire airfield environment, including movement and non-movement areas, to improve safety at airports hosting air carrier operations. After reviewing the comments received and conducting further internal analysis, the FAA is amending that proposal. The FAA now proposes to require an SMS only for a certificated airport classified as a small, medium, or large hub airport in the National Plan of Integrated Airport Systems; serving international air traffic; or having more than 100,000 total annual operations. The FAA is also proposing changes that would extend the implementation period from 18 to 24 months; require submission of an implementation plan within 12 months instead of 6 months of the effective date of the final rule; modify the training requirements; ensure consistency among various FAA SMS initiatives, and reduce the implementation burden.

DATES: Send your comments on or before September 12, 2016.

ADDRESSES: You may send comments identified by Docket Number FAA–2010–0997 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Bring comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: In accordance with 5 U.S.C. 553(c), the Department of Transportation (DOT) solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: To read background documents or comments received, go to *http://www.regulations.gov* and follow the online instructions for accessing the docket. Or, go to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this proposed rule, contact Keri Lyons, Office of Airports Safety and Standards, Airport Safety and Operations Division, AAS–300, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8972; email *keri.lyons@faa.gov.*

SUPPLEMENTARY INFORMATION: Later in this preamble under the Additional Information section, we discuss how you can comment on this proposal and how we will handle your comments. This discussion includes related information about the docket, privacy, and the handling of proprietary or confidential business information. We also discuss how you can get a copy of this proposal and related rulemaking documents.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

The FAA is proposing this rulemaking under the authority described in Subtitle VII, part A, subpart III, section 44706, "Airport operating certificates." Under that section, Congress charges the FAA with issuing airport operating certificates (AOC) that contain terms that the Administrator finds necessary to ensure safety in air transportation. This proposed rule is within the scope of that authority because it requires certain certificated airports to develop and maintain an SMS. The development and implementation of an SMS ensures safety in air transportation by assisting these airports in proactively identifying and mitigating safety hazards.

I. Executive Summary

A. Purpose of This SNPRM

The increasing demands on the U.S. air transportation system, including additional air traffic and surface operations and airport construction, have the potential to heighten risk to operating aircraft. Historically, the approach to aviation safety was based on the reactive analysis of past accidents and the introduction of corrective actions to prevent the recurrence of those events. An SMS, however, helps airport operators to proactively identify potential hazards in the operating environment, analyze the risks of those hazards, and mitigate those risks to prevent an accident or incident. In its most general form, SMS is a set of decision making tools that an airport operator would use to plan, organize, direct, and control its everyday activities in a manner that enhances safety.

On October 7, 2010, the FAA published an NPRM entitled "Safety Management System for Certificated Airports" (75 FR 62008). In the NPRM, the FAA proposed to require all 14 Code of Federal Regulations (CFR) part 139 certificate holders to establish an SMS to improve the safety of their aviation-related activities.

The FAA received 65 comments in response to the NPRM from a variety of commenters. Because of the complexity of the issues and concerns raised by the commenters, the FAA began to reevaluate whether deployment of SMS at all certificated airports was the most effective approach. As part of this process, the FAA looked at applicability for various categories of certificate holders to determine which option would maximize safety benefits in the least burdensome manner. While the FAA is proposing a preferred alternative in this SNPRM, the FAA requests comments on the other applicability alternatives discussed in this SNPRM.

The preferred alternative harmonizes with the intent of ICAO SMS standards by including all certificated airports accepting international operations. The FAA supports conformity of U.S. aviation safety regulations with ICAO standards and recommended practices and believes the SNPRM meets the intent of the ICAO standard in a way that complements existing airport safety regulations in part 139.

The FAA continues to believe that an SMS can address potential safety gaps through improved management practices.[1] SMS's proactive emphasis on hazard identification and mitigation, and on communication of safety issues, would provide certificate holders with robust tools to improve safety. While the comments generated some changes to the proposal in this document, most of the proposed core elements of the SMS program remain in this SNPRM.

B. Summary of the Major Provisions of the SNPRM

The major change in this SNPRM is to the proposed applicability. Rather than requiring an SMS at all certificated airports, the FAA now proposes to require an SMS be developed, implemented, maintained, and adhered to at any certificated airport:

- Classified as a small, medium, or large hub[2] airport in the National Plan of Integrated Airport Systems (NPIAS);[3]
- Identified by the U.S. Customs and Border Protection (CBP) as a port of entry (under 19 CFR 101.3), designated international airport (under 19 CFR 122.13), landing rights airport (under 19 CFR 122.14), or user fee airport (19 CFR 122.14) (collectively referred to throughout this proposal as "international airports"); or
- Identified as having more than 100,000 total annual operations (according to best available data).

Additionally, the FAA proposes extending the implementation period from 18 to 24 months, requiring submission of an implementation plan within 12 months instead of 6 months of the effective date of the final rule, and changes to the training requirements. Other changes have also been made to ensure consistency among various FAA SMS initiatives and to reduce the implementation burden.

Throughout the document, the FAA requests specific comment on the following issues:

- What other methods may be available to accurately account for and determine applicability based on annual operations or whether the FAA should use a different baseline for determining applicability;
- What other methods may be available to identify international airports;
- What types of data or other information certificated airports could provide under a national reporting database;
- Whether the estimates of the average pool of employees needing comprehensive SMS training is an accurate average across all airports affected by the proposal;
- What types of job roles would require comprehensive SMS training; and
- Whether the implementation of the proposed accountable executive definition is feasible.

C. Summary of the Costs and Benefits

This proposed rule would require certain certificate holders under part 139 to establish an SMS. SMS is a set of tools designed to help airports effectively integrate formal risk control procedures into normal operational practices to improve operational safety. Benefits are estimated at $370.8 million ($225.9 million present value) and total costs are estimated at $238.9 million ($157.5 million present value), with benefits exceeding costs. The following table shows benefits and costs of the alternatives over 10 years.

Base case	All ($)	Class I ($)	International ($)	L, M, S and >100K ops ($)	Preferred alternative: L, M, S, >100K ops, and international ($)
Benefits	$382,987,281	$368,096,671	$360,907,166	$356,128,301	$370,788,457
Costs	471,104,787	341,021,606	215,010,997	163,760,850	238,865,692
Net Benefits	−88,117,506	27,075,065	145,896,169	192,367,451	131,922,764
PV Benefits (7%)	233,282,770	224,210,033	219,830,291	216,919,352	225,850,869
PV Costs (7%)	307,842,595	223,584,687	141,796,001	108,819,973	157,496,312
PV Net Benefits (7%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557
PV Benefits (3%)	307,499,272	295,542,114	289,769,378	285,932,407	297,704,052
PV Costs (3%)	389,440,320	282,304,199	178,432,284	136,340,226	198,211,977
PV Net Benefits (3%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557

Mitigation Costs: Not quantified, estimates not included.
Given the range of mitigation actions possible, it is difficult to quantify potential benefits.

The estimated costs of this rule do not include the costs of mitigations that operators could incur as a result of conducting the risk analysis proposed in this rule. Given the range of mitigation actions possible, it is difficult to provide a quantitative estimate of both the costs and benefits of such mitigations. We anticipate that operators will only implement mitigations where benefits of doing so exceed the costs of mitigations. In order for the estimated benefits to exceed the costs of the rule, the mitigation costs must be below $68.4 million over 10 years (discounted at 7%). The FAA requests comment on this assumption, as well as data regarding costs and benefits associated with any mitigations implemented through voluntary SMS programs.

---

[1] Additional information regarding the purpose of the proposed SMS requirement can be found in the "Background" section of the NPRM (75 FR 62008).

[2] The FAA's use of the term hub airport is different than that of airlines, which use the term to denote an airport with significant connecting traffic by one or more carriers. As defined in 49 U.S.C. 47102, large hubs are those airports that account for 1 percent or more of total U.S. passenger boardings (U.S. passenger enplanements); medium hubs are airports that account for between 0.25 percent and 1 percent of total U.S. passenger boardings; and small hubs are airports that enplane 0.05 percent to 0.25 percent of total U.S. passenger boardings.

[3] The Secretary of Transportation is required to maintain a plan for developing public-use airports that are important to the national transportation system. The NPIAS identifies the types of projects and estimated costs eligible for federal financial assistance necessary to provide a safe, efficient, and integrated system of airports. The FAA Office of Airports maintains the NPIAS and publishes a *Report to Congress* every other year. Current and past reports are available at *http://www.faa.gov/airports/planning_capacity/npias/*.

II. Background

A. NPRM

In the NPRM, the FAA proposed to require all part 139 certificate holders to develop and implement an SMS to improve the safety of their aviation-related activities. An SMS is a formalized approach to managing safety by developing an organization-wide safety policy, developing formal methods of identifying hazards, analyzing and mitigating risk, developing methods for ensuring continuous safety improvement, and creating organization-wide safety promotion strategies.

The original comment period was to close on January 5, 2011, but, in response to several commenters' requests, the FAA extended the comment period to July 5, 2011. Additionally, the FAA permitted commenters to submit clarifying questions to the docket during the comment period. The FAA answered these questions before the comment period closed in a document that was placed in the docket (the "Responses to Clarifying Questions").[4] The FAA also published a technical report detailing results of the Office of Airports' SMS pilot studies that was also placed in the docket.[5]

In the NPRM, the FAA proposed a new subpart E that would have: (i) Required all holders of an airport operating certificate (AOC) to have an approved airport SMS; (ii) prescribed the components of an SMS; and (iii) prescribed implementation requirements for an airport SMS. Certificate holders would have implemented SMS throughout the airport environment, including the movement and non-movement areas (*e.g.,* runways, taxiways, run-up areas, ramps, apron areas, and on-airport fuel farms).

Under the proposal, the FAA envisioned an SMS as an adaptable and scalable system. For example, the proposal permitted certificate holders to maintain a separate SMS manual in addition to the Airport Certification Manual (ACM), or maintain SMS documentation directly in the ACM. Options such as these would have permitted certificate holders that operate multiple airports maximum flexibility in the development of their SMS. Similarly, the proposal included a requirement for certificate holders to establish a system for identifying safety hazards and a systematic process to analyze hazards and their associated risks. By not prescribing any one means for identifying hazards or analyzing risk, the proposal permitted certificate holders flexibility in developing scalable and adaptable processes under their SMS.

B. Summary of Comments on NPRM

The FAA received 65 comments in response to the NPRM from a variety of commenters including air carriers, airport operators/certificate holders, representatives of airline employees, trade associations, an airport user group, attorneys general, consultants, universities and private citizens. Commenters included:

- *Air carriers:* Delta Airlines,
- *Airport operators/certificate holders:* Alaska Department of Transportation and Public Facilities, Austin-Bergstrom International Airport (TX), Bangor International Airport (ME), City of Albuquerque (NM), City of Merced (CA), City of Phoenix (AZ), City of Prescott (AZ), Clark County Department of Aviation (NV), Coastal Carolina Regional Airport (NC), Columbus Regional Airport Authority (OH), Contra Costa County (CA), Dallas/Fort Worth International Airport (TX), Denver International Airport (CO), Floyd Bennett Memorial Airport (NY), Glynn County Airport Commission (GA), Hartsfield-Jackson Atlanta International Airport (GA), Houston Airport System (TX), Huntingburg Airport (IN), Indianapolis Airport Authority (IN), Jacksonville International Airport (FL), Lee County Port Authority (FL), Louisville Regional Airport Authority (KY), Manchester-Boston Regional Airport (MA), March Inland Port Authority (CA), Maryland Aviation Administration (MD), Miami-Dade Aviation Department (FL), Modesto City-County Airport (CA), Myrtle Beach International Airport (SC), Norm Y. Mineta San Jose International Airport (CA), Pitkin County (CO), Pittsburgh International Airport (PA), Port Authority of New York and New Jersey (NY/NJ), Port of Portland (OR), Rapid City Regional Airport (SD), Rochester Airport Company (MN), San Antonio Airport System (TX), Santa Barbara Airport (CA), Tri-Cities Regional Airport (TN), Tucson Airport Authority (AZ), Tulsa Airport Authority (OK), Wayne County Airport Authority (MI),
- *Representatives of airline employees:* Airline Pilots Association (ALPA),
- *Trade associations:* Airlines for America (A4A), Aircraft Owners and Pilots Association (AOPA), Airports Council International-North America (ACI–NA), American Association of Airport Executives (AAAE), American Association for Justice (AAJ), Colorado Airport Operators Association (CAOA), Experimental Aircraft Association (EAA), National Air Transportation Association (NATA),
- *Airport users groups:* Prescott Airport Users Association,
- *Attorneys General:* Attorney General for the District of Columbia, Attorney General for the State of Oklahoma,
- *Consultants and universities:* Landry Consultants and Dave Fleet Consulting, Purdue University, the University of Southern California Aviation Safety and Security Program (U.S.C.), and
- Eight individuals and 9 anonymous submissions.

One individual submitted a comment that was out-of-scope, and portions of Clark County, Dallas-Fort Worth International, and AOPA's submissions were out-of-scope.

In addition to the above, the FAA received clarifying questions from the following entities during the comment period: AAAE, ACI–NA, Austin-Bergstrom International Airport, Fairbanks International Airport, Fresno Yosemite International Airport, Landry Consultants and Dave Fleet Consulting, Louisville Regional Airport Authority, Maryland Aviation Administration, Port of Seattle, and U.S.C.. The FAA answered these questions in the Responses to Clarifying Questions.[6] Those questions are not addressed in this document.

C. Need for SNPRM

While reviewing the comments to the NPRM, the FAA began to re-evaluate whether requiring an SMS at all certificated airports was the most effective option. As part of this process, the FAA looked at the applicability for various categories of certificate holders to determine which option would maximize safety benefits in the least burdensome manner. While the FAA is proposing a preferred alternative in this SNPRM, the FAA requests comments on the other applicability alternatives discussed in this SNPRM.

---

[4] *"FAA Responses to Clarifying Questions About Proposed Rulemaking for SMS for Certificated Airports"* is available at *http://www.regulations.gov/#!documentDetail;D=FAA-2010-0997-0073*).

[5] *Safety Management System Pilot Studies (Technical Report)* is available at *http://www.regulations.gov/#!documentDetail;D=FAA-2010-0997-0074*.

[6] FAA Responses to Clarifying Questions (May 24, 2011), *available at http://www.regulations.gov/#!documentDetail;D=FAA-;2010-0997-0073*.

III. Discussion of Proposals in the SNPRM

A. Differences Between the SNPRM and the NPRM

1. Applicability

In the NPRM, the FAA proposed that all 544[7] certificated airports be covered by the SMS requirements.

Based on comments and other information gathered, it became evident that application of SMS across all certificated airports was not practical. In response, the FAA revised its assumptions used to calculate overall costs associated with this SNPRM's proposal. The FAA also reviewed additional accident and incident databases to obtain more accurate assumptions of benefits derived from an SMS. These additional databases included the FAA Accident and Incident Database (AIDS), NASA's Aviation Safety Reporting System (ASRS), the FAA's Wildlife Strike Database, and the FAA's Runway Incursion Database.

Using these revised cost and benefit estimates, the FAA considered a range of alternatives to determine how to apply an SMS requirement that would reduce risk at the largest group of airports while still producing net benefits. The FAA focused on airports with the highest passenger enplanements and largest total operations so that safety benefits would flow to the overwhelming majority of aircraft operations in the United States. The FAA also focused on incorporating airports with international passenger operations to ensure conformity with international standards and recommended practices. To that end, the FAA developed the following alternatives for additional analysis:

- All part 139 airports (as originally proposed) (544 airports covering 99.8% of U.S. passenger enplanements);
- Airport operators holding a Class I AOC (388 airports covering 99.7% of U.S. passenger enplanements);
- Certificated international airports (240 airports covering 96.1% of U.S. passenger enplanements);
- Large, medium, and small hub airports (as identified in the NPIAS) and certificated airports with more than 100,000 total annual operations (177 airports covering 97.5% of U.S. passenger enplanements); and
- Large, medium, and small hub airports, certificated airports with more than 100,000 total annual operations, and certificated international airports (268 airports covering 98% of U.S. passenger enplanements).

Because the FAA chose to analyze various alternatives based on classifications outside the scope of part 139 (*e.g.*, hubs or international status instead of AOC class), it relied on the best available information to develop the list of affected airports under each alternative. To identify those airports classified as large, medium, or small hubs, the FAA relied on the 2011–2015 NPIAS, current at the time of this analysis. Similarly, the FAA relied on annual operations data reported through FAA Form 5010–1, Airport Master Record (downloaded August 1, 2012). The FAA relied on data obtained from Title 19 of the CFR (*see* §§ 101.3, 122.13, 122.14, 122.15) and the CBP to identify certificated airports authorized to accept international traffic.

After reviewing each of the alternatives and the associated costs and benefits of each, the FAA's preferred proposal would require an SMS be developed, implemented, maintained, and adhered to only at a certificated airport:

- Classified as a small, medium, or large hub airport in the NPIAS; or
- Identified as an international airport; or
- Identified as having more than 100,000 total annual operations.

This preferred alternative covers 268 airports across Classes I, II, III, and IV, thus eliminating the NPRM's SMS requirements for 276 airports that have few passenger enplanements and less complex operations. The airports that comprise this alternative account for over 98% of all passenger enplanements in the U.S.

While simply applying the proposed SMS requirements to large, medium, and small hub-certificated airports would account for most of this traffic, many critical airports would not be included because they do not meet those enplanement thresholds. Simply accounting for airports with higher passenger enplanements fails to acknowledge the many other complex, certificated airports that have significant levels of aircraft operations.[8] Therefore, to ensure that these busy airports are covered by the proposal, the preferred alternative includes airports with more than 100,000 total annual operations based on their operations data submitted through FAA Form 5010–1, Airport Master Record available on August 1, 2012. The FAA acknowledges that data submitted through FAA Form 5010–1 may be estimates for airports that do not have an air traffic control tower. While more definitive data may be available through the FAA's air traffic control tower counts, this information may not be readily available, may not be accessible to the public, and does not account for certificated airports that do not have an air traffic control tower. The FAA requests comments on what other methods may be available to accurately account for and determine the proposed rule's applicability based on annual operations, or whether the FAA should use a different baseline for determining applicability.

The preferred alternative also harmonizes with the intent of International Civil Aviation Organization (ICAO) SMS standards by including all certificated airports accepting international operations. In December 1996, the FAA published Advisory Circular (AC) 150/5000–5C, Designated U.S. International Airports, which explained the different categories of U.S. airports designated to serve international air traffic and provided a list of those airports. However, the FAA cancelled that AC in September 2010 when it published AC 150/5000–16, Announcement of Availability of the Guide for Private Flyers—U.S. International Airports. The Guide for Private Flyers, published by the CBP, lists all U.S. international airports, designated airports, landing rights airports, and user fee airports. It also defines the term "international airport" and clarifies the use of the word "international" in an airport name. Since the FAA no longer maintains its own list of international airports, the FAA believes the CBP list serves as the best available source of this information because it is developed based on Title 19 (Customs Duties) of the CFR. The FAA believes this approach corresponds with the intent of ICAO Annex 14 standards. The FAA requests comments on this approach, and what other methods may be available to identify international airports.

The FAA acknowledges that an airport's status in any one of these categories may change over time. For example, a small hub airport may become a nonhub airport during the FAA's annual update of passenger enplanement data if its enplanements fall below 0.05% of the total U.S. passenger enplanements. Similarly, an airport not currently considered a hub might see its enplanements increase making it a small hub. The same case could be made for annual operations and international status.

---

[7] The number of certificated airports at the time of SNPRM development.

[8] Section V(B), Applicability contains detailed analysis of these alternatives.

In these cases, the FAA would review each airport's status annually,[9] consistent with published enplanement data,[10] to determine which airports are covered by the SMS requirement then in effect. If there is a change to an airport's status that affects its need to comply with those SMS requirements, the FAA would then notify the certificate holder in writing of its changed status. If the change would require the certificate holder to comply with those SMS requirements, the certificate holder would then have two years to comply with the SMS requirements then in effect. Certificate holders whose status changed to be outside the scope of the SMS requirements then in effect would be encouraged to voluntarily maintain and adhere to an SMS. The FAA would maintain a list of those certificate holders meeting the required applicability on its public Web site, updating the list annually.

The FAA requests comment on this approach. Specifically, if a certificate holder meets the threshold to trigger an SMS requirement, should the certificate holder be required to maintain an SMS even if it no longer meets the threshold? Should a certificate holder meet the applicability threshold for two consecutive years prior to triggering an SMS requirement?

2. Implementation

Under this proposal, certificate holders would be required to develop and implement an SMS within 2 years of the effective date of the final rule. The NPRM originally proposed SMS implementation within 1 year from the effective date of the final rule. This change responds to commenters' requests for additional time to implement SMS.

The FAA recognizes the complexity of implementing SMS in the airport environment and, therefore, increased the timeframes for implementation. The FAA requests comments whether this proposed implementation timeframe is sufficient. Comments should be supported by specific data demonstrating a different implementation timeframe is necessary.

3. Training

The NPRM proposed an SMS training requirement for all employees and tenants with access to the movement and non-movement areas of the airport. To maximize the potential for proactively identifying hazards, the intent was to ensure that individuals authorized access to the movement and non-movement area received training. The FAA's intent was to create a broad training requirement, allowing certificate holders flexibility in how they trained persons with access to these areas. This flexibility included allowing train-the-trainer programs and training specific to the person's role in the SMS. This would allow certificate holders to provide orientation to the majority of persons accessing the non-movement and movement areas of hazard identification and reporting, rather than training on all of the certificate holder's SMS initiatives.

Commenters appear to have interpreted the proposed training requirement to be cumbersome, time consuming, and excessively costly. In light of these comments and lessons learned from the pilot studies, this proposal offers a two-pronged approach to training: (i) Comprehensive SMS training specific to the individual's role and responsibility in implementation and maintenance of the SMS; and (ii) hazard awareness and reporting awareness orientation for all other individuals with access to the movement and non-movement areas.

The FAA expects certificate holders to provide training appropriate to the person's role in the certificate holder's SMS. For example, those persons responsible for analyzing hazard reports to determine action should be properly trained in Safety Risk Management (SRM) and hazard assessment procedures. Individuals, including staff and/or managers, with responsibility for daily oversight of the SMS would be trained in all requirements of the SMS. The certificate holders could use train-the-trainer formats where necessary.

By clarifying this proposed requirement, the FAA anticipates that, on average, 10 employees or managers would need this training at large airports and 3 employees or managers would require it at small airports.[11] The supplemental initial regulatory evaluation uses these estimates in the cost analysis. The FAA requests comments on whether these estimates are accurate as an average across all airports affected by this proposal. The FAA acknowledges that there may be certificate holders included in the preferred applicability alternative who have smaller staffs than these numbers take into account. The FAA also requests comments on the job roles that would require this type of specific training.

For the remaining persons with access to the movement and non-movement areas, certificate holders could use a variety of means to provide awareness. For example, a certificate holder could develop a brochure or white paper for inclusion in the employee's indoctrination package, or add a reference to hazard identification and reporting to existing training programs such as security or driver training.

The certificate holder would bear the cost of publishing this awareness material and updating it as necessary. For persons employed by tenants, the certificate holder would be responsible for providing the materials to the tenants for distribution. Tenants, such as air carriers, caterers, fueling agents, and FBOs, all would potentially receive this information if their employees access the movement or non-movement areas. However, the certificate holder could choose to provide this material or briefings during badging or security training.

There should be minimal record-keeping costs associated with this type of training/awareness. The FAA anticipates that certificate holders would retain copies of the materials provided and a distribution log detailing when the materials are provided to employees and tenants.

The FAA does not intend for the proposed requirement to apply to persons escorted by a trained individual. As for an air carrier's crewmember training, those individuals authorized to enter the movement and non-movement areas unescorted would receive training appropriate to their role; in this case, awareness of hazard identification and reporting. The air carrier would then distribute the materials provided by the certificate holder.

While the NPRM did not explicitly propose recurrent training, the FAA envisioned the need for certificate holders to provide individuals with updated information, all in support of a positive safety culture. This proposal includes a requirement for recurrent training every other year. It also would require the update of publications for the hazard awareness orientation requirement on the same schedule.

4. Definition of Accountable Executive

Numerous commenters thought the definition of accountable executive proposed in the NPRM was impractical and needed to be revised. After considering these comments, the FAA agrees that the proposed definition will present compliance and operational challenges in the U.S. airport environment. Therefore, in this SNPRM, the new proposed definition (i) eliminates the substantive differences between the part 121 and part 139 definitions, and (ii) clarifies that the accountable executive should not be personally liable to the FAA through certificate action or civil penalty. The FAA requests comment on the feasibility of implementing this proposed definition.

---

[9] The Office of Airports regularly tracks the status of certificated airports. As such, this review would result in an insignificant increase in cost based on current FAA oversight activities.

[10] This data is available online at *http://www.faa.gov/airports/planning_capacity/passenger_allcargo_stats/passenger/*. Passenger enplanement data is gathered from the Air Carrier Activity Information System (ACAIS).

[11] As discussed in the Supplementary Initial Regulatory Evaluation, the analysis classifies large, medium, and small hub airports as large airports and all others as small airports.

B. Proposals Remaining From NPRM

As proposed in the NPRM, the certificate holder's SMS would be required to contain the following four components: Safety policy, safety risk management, safety assurance, and safety promotion. To satisfy the safety policy component, the certificate holder would establish a policy which, among other things, defines the certificate holder's safety objectives, establishes a safety policy statement, defines the certificate holder's management responsibilities and accountabilities for safety issues, and identifies and communicates the organization's structure for handling safety issues.

The certificate holder would also be required to designate an accountable executive, within the certificate holder's own organization or governance structure, who would act on its behalf in overseeing the implementation and daily operation of the SMS. For most airports, the FAA anticipates the accountable executive would be an airport manager or airport director rather than a lower level manager or supervisor.

Under safety risk management, the certificate holder would develop processes to identify hazards that may impact the airport's operations. The certificate holder would use these processes to systematically analyze those hazards and their risks, as well as proactively mitigate risk unacceptable to the certificate holder. The certificate holder would retain any documentation developed through these processes to assist in trend and root cause analysis.

Through safety assurance, the certificate holder would develop and implement processes to monitor the safety performance of its SMS. Additionally, the certificate holder would establish and maintain a hazard reporting system that provides reporters confidentiality when communicating safety issues to the system. The certificate holder's staff would regularly update the accountable executive on pertinent safety information such as the certificate holder's compliance with part 139 subpart D requirements, and its performance with regard to its safety objectives, safety critical information, the status of any ongoing mitigations established through safety risk management, and the status of implementing the SMS.

Under safety promotion, the certificate holder would identify managers and staff employees responsible for oversight and implementation of the SMS and would provide training on their SMS responsibilities. These individuals would receive recurrent training every 24 months. For all other individuals with regular access to the movement and non-movement areas of the airfield, the certificate holder would develop and distribute hazard reporting and awareness orientation materials, ensuring those individuals are made aware of hazards and how to report them to the certificate holder's hazard reporting system. The certificate holder would then keep records of training provided and hazard reporting and awareness orientation materials for 24 calendar months.

The certificate holder would also be required to develop processes and procedures to communicate important safety information that ensures all persons authorized access to the movement and non-movement areas are aware of the SMS and their safety roles and responsibilities. Feedback would be provided to individuals using the certificate holder's hazard reporting system. Lessons learned that are relevant to airport employees or stakeholders also would be communicated.

The certificate holder would have the option of either developing and maintaining a separate SMS manual in addition to the Airport Certification Manual (ACM), or incorporating these proposed requirements directly in the ACM. If the certificate holder develops a separate SMS manual, it would cross-reference the SMS requirements in its FAA-approved ACM.

IV. Discussion of Comments Received on NPRM

A. FAA Rulemaking Authority

The NPRM proposed implementing SMS throughout the airport environment, including the movement and non-movement areas (*e.g.,* runways, taxiways, run-up areas, ramps, apron areas, and on-airport fuel farms). In the NPRM, the FAA acknowledged the proposal extended the scope of part 139 by including the non-movement area but concluded that ensuring air transportation safety required that an SMS apply to any place that affects safety during aircraft operations. An association and a certificate holder noted that the application of SMS to the non-movement area is an unprecedented expansion of the FAA's regulatory scope.

The FAA has authority under 49 U.S.C. 44706 to issue AOCs that contain terms to ensure safety in air transportation. The FAA acknowledges that it has historically focused its regulatory practice on the movement area. However, the statutory authority encompasses the entire airport operating environment, which includes the non-movement area. The proposed requirement to develop and implement an SMS ensures safety in air transportation by assisting certificate holders in proactively identifying and mitigating safety hazards. Furthermore, as discussed later, findings from the SMS pilot studies and the large number of safety incidents occurring in the non-movement area support extending SMS to the non-movement area to ensure safety in air transportation.

Accordingly, as stated in the NPRM, this proposal, to the extent it would apply to both the movement and non-movement areas, is within the FAA's statutory authority.

B. Applicability

The NPRM proposed requiring all certificate holders, including airport operators holding a Class I, II, III, or IV AOC, to develop and implement an SMS for the movement and non-movement areas of the airport. One Class IV certificate holder recommended that the FAA require SMS only at airports holding a Class I AOC, stating this would target the majority of air carrier passengers in the U.S. and allow small airports to avoid costly burdensome regulations. The certificate holder recommended a voluntary program for Class II, III, and IV certificate holders.

The FAA partially agrees with the commenter. The FAA believes all certificate holders would realize benefits from formalized hazard identification, risk analysis, training and communications processes. However, further review of costs and benefits indicate that, for certificate holders with fewer operations, the costs of SMS implementation may be disproportionate to the benefits realized. The FAA continues to evaluate means to reduce costs for smaller airports, but, in the absence of significant regulatory cost reductions, the FAA's preferred proposal is to require SMS implementation at large, medium, and small hub airports, certificated airports with more than 100,000 total annual operations, and certificated international airports.

Requiring an SMS for only the largest and most complex of operations will enhance safety at airports receiving 98% of all passenger enplanements. The revised proposed rule would apply to 268 airports, thus eliminating the burden on 276 airports that have few passenger enplanements and less complex operations.[12] This proposed requirement advances the FAA's safety goals and at the same time reduces the burden imposed by the NPRM. Although not proposing to require SMS implementation at all certificated airports, the FAA encourages all certificate holders to voluntarily implement SMS based on this proposed rule and accompanying agency guidance.

Besides the alternative proposed in this SNPRM and the proposal in the NPRM, the FAA analyzed a variety of other applicability scenarios including:

- Airport operators holding a Class I AOC;
- Certificated international airports; and,
- Large, medium, and small hub airports and certificated airports with more than 100,000 total annual operations.

i. Airport Operators Holding a Class I AOC

Since the last major revision to part 139, the FAA typically has applied technical requirements based on AOC class. Consistent with this past practice, the FAA first analyzed limiting applicability to Class I certificate holders. When reviewed as a whole, the 388 airports identified as holding a Class I AOC (as of October 2012) account for 99.7% of the total U.S. passenger enplanements as of the end of calendar year 2011. All certificated airports account for 99.8% of the total U.S. passenger enplanements, a difference of 0.1%. However, the list fails to account for many busy airports by total annual operations (not passenger enplanements), some of which receive more total annual operations than some Class I airports. Class I certificate holders also appear to include many smaller airports that support only domestic operations. For these reasons, the FAA does not believe that limiting applicability to Class I certificate holders alone is the best way to enhance safety through SMS.

ii. Certificated International Airports

The FAA also analyzed certificated international airports. Limiting the scope to these airports meets the intent of the ICAO standard. In the NPRM, the FAA addressed the ICAO standard by proposing all certificate holders implement an SMS. However, many commenters expressed concerns about the expansion of applicability beyond the ICAO standard (*i.e.*, applying the standard to airports serving only domestic traffic). The FAA identified 240 certificated airports with international services (as of August 1, 2012). Relying on data prepared by the CBP, these 240 airports encompass all certificated airports that serve as ports of entry, designated international airports, landing rights airports, and user fee airports.

These international airports account for 96.1% of the total U.S. passenger enplanements (as of the end of calendar year 2011). While these airports account for the vast majority of international operations within the U.S., this scenario fails to capture some of the nation's busiest airports that accept only domestic operations. Based on the limitation of applicable airports under this scenario, the FAA does not believe that limiting applicability to international airports is a viable option to achieve the most safety benefit.

iii. Large, Medium, and Small Hub Airports and Certificated Airports With More Than 100,000 Total Annual Operations

The FAA also analyzed airports by their NPIAS category, looking at the airports that receive the vast majority of enplanements, otherwise known as hubs. Including only large, medium, and small hub airports does not capture airports receiving large numbers of total annual operations. Therefore, the FAA included in its analysis of this scenario certificated airports with more than 100,000 total annual operations according to their Airport Master Record, FAA Form 5010–1 (available on August 1, 2012).

This grouping gets much closer to the goal of accounting for the most complex, busiest and highest passenger enplanements throughout the country. Using this grouping for applicability would include 177 certificated airports that account for 97.5% of total U.S. passenger enplanements, and all certificated airports having more than 100,000 total annual operations. The FAA believes this alternative achieves the goal of integrating safety management practices into the most complex, highest operation and passenger enplanement airports. Also, of those alternatives for which FAA has estimated benefits and costs, this alternative has the highest estimated net benefits. However, this alternative does not harmonize with ICAO standards because 91 international airports would not be required to implement an SMS, which could expose small international airports to the risk that international carriers refuse to operate there. Opting out would also require the FAA to file a difference with international standards.

iv. Preferred Alternative

The FAA now proposes to require an SMS be developed, implemented, maintained, and adhered to at any certificated airport:

- Classified as a small, medium, or large hub airport;
- Identified as an international airport; or
- Identified as having more than 100,000 total annual operations.

This preferred alternative ensures that safety management practices will be integrated into the busiest airports and harmonizes with international standards. This alternative applies to 268 airports, encompassing 98% of total U.S. passenger enplanements. In addition, this alternative positively responds to the commenters' requests to limit applicability.

On the other hand, including the additional 91 small international airports that would not be captured by the preceding alternative reduces the estimated net benefits of the rule. This is largely due to the small number of reported accidents at these 91 airports. However, FAA's analysis does not consider the possibility that international airports without SMS risk losing international business due to a lack of compliance with ICAO standards. If this were to occur, airlines and other operators would incur costs to re-route to suboptimal locations. The magnitude of this potential effect is uncertain, as it would depend on the decisions of foreign actors to cease operations to domestic airports without a compliant SMS. FAA welcomes comments on this issue.

v. Large, Medium, and Small Hub Airports; Certificated Airports With More Than 100,000 Total Annual Operations; and an Optional Certificate of Compliance Program for Airports With Less Than 100,000 Annual Operations

The FAA is also seeking comment on an alternative featuring an optional certificate of compliance program for airports that aren't required to implement an SMS, but is otherwise identical to the alternative discussed in part iii of this section. This option would allow airports with less than 100,000 annual operations to choose to implement a compliant SMS if they believe the benefits to them will outweigh the costs to them.

---

[12] These figures are current as of October 2012.

This alternative mitigates the concern that small international airports would suffer a decline in their international traffic due to a lack of compliance with ICAO's SMS standards, as airports could implement a compliant SMS if they so choose. Providing choice to these airports should also lead to higher net benefits than the preferred alternative, as those airports where the benefits of SMS do not exceed the costs can forego those costs.

As previously stated, this alternative could present business risks to those small airports choosing to not implement a compliant SMS. Civil aviation authorities could prohibit their international air carriers from serving non-compliant airports. Similarly, the FAA could receive unsatisfactory audit findings with additional potential unforeseen consequences for failure to conform to international standards.

vi. Inactive Airports

Another Class IV certificate holder and an association requested the FAA not require certificate holders in an "inactive status," or with a Limited AOC, to have an SMS.

Placement in an "inactive" status simply defers the FAA's annual periodic inspections. That way, the agency can focus its efforts on certificate holders with active air carrier service. However, certificate holders in an inactive status must continue to meet all part 139 requirements. As of May 2013, of the fourteen airports in an inactive status, only two would fall under the proposed applicability standards. If a certificated airport was later placed in an "inactive" status, it would still be required to comply with the proposed SMS requirements if it met the applicability requirements of this proposal.

As for the commenters' request about Limited AOCs, the FAA no longer issues Limited AOCs. Therefore, this issue is moot.

vii. Adherence to SMS

This SNPRM also proposes changes to § 139.401(a) to specify that the certificate holder must adhere to an airport SMS. While the FAA received no comments regarding this issue, the FAA believes that adding "adhere to" emphasizes the point that an SMS is an ongoing obligation and should not be shelved after implementation. Further, it adds distinction between the phases of SMS from development to implementation to maintenance to adherence.

viii. Scalability

The majority of commenters, including certificate holders and associations, commented both directly and indirectly on the need for scalability and flexibility when developing and implementing an SMS.

To address those comments and harmonize with other FAA rules, the FAA proposes a new § 139.401(c) permitting scalability of an SMS based on the size, nature, and complexity of the operations, activities, hazards and risks associated with the certificate holder's operations.

C. Implementation Deadlines and Phasing

The NPRM included a two-pronged approach to implementation based on the certificate holder's AOC class. Certificate holders with a Class I AOC would have developed an implementation plan and SMS manual and/or ACM update within 6 months and 18 months of the final rule's effective date. Under the NPRM, all other certificate holders would have 9 months and 24 months, respectively, to develop an implementation plan and SMS manual and/or ACM update. The NPRM did not propose any other implementation approach.

Twenty-six commenters, including five associations, twenty certificate holders, and one consultant offered comments about the FAA's proposed implementation deadlines and the lack of phasing. These commenters generally recommended a phased approach, citing pilot study findings, ICAO's recommended approach, the Airport Cooperative Research Program SMS Guidebook, and the FAA's internal SMS policies. A phased approach usually includes implementing SMS through a series of management steps, such as (1) planning and organization, (2) basic safety management, (3) fully functional SMS, and (4) continuous improvement.

In addition to a phased approach, fourteen commenters, including three associations and eleven certificate holders, believed the deadlines for submitting the implementation plan and implementing SMS were not adequate. Four certificate holders and one association believed the proposed deadlines were aggressive. Two other certificate holders commented that the implementation plan deadline is not adequate based on the complexity and lack of familiarity with SMS concepts. Two certificate holders stated that it would be difficult, if not impossible, to procure consultant assistance within the proposed timeframes associated with the implementation plan.

Two certificate holders stated that if the FAA includes the non-movement area in the final rule, the implementation deadlines should be extended and phased. Furthermore, an association and several certificate holders believed the FAA should require implementation of SMS in the movement area, or those areas already covered under part 139, before requiring SMS in the non-movement area. Doing so would allow certificate holders time to renegotiate lease agreements where necessary, update airport rules and regulations or minimum standards, and use lessons learned for applying SMS to the non-movement area.

One commenter contended that large airports needed as much time as smaller airports to implement SMS, and that two different implementation schedules based on AOC class was not justified. Similarly, an association did not believe the FAA explained why Class I airports need less time to implement SMS than small certificated airports that may have a less complex system to analyze and less cumbersome requirements to adopt.

Nine certificate holders, one association, and one consultant provided implementation schedules which can be summarized into the following three general recommendations:

(1) Longer deadlines after the effective date of the rule for developing implementation plans (ranging from 9 to 18 months for Class I certificate holders, and 12 to 18 months for all other certificate holders), and SMS manuals and/or ACM updates (ranging from 24 to 60 months for Class I certificate holders and 36 months for all other certificate holders);

(2) Phased implementation over the course of 63 months for all certificated airports; and

(3) Airport-centric implementation, which would allow each certificate holder to propose its own phased approach to implementation within reasonable timeframes.

One certificate holder requested the FAA clarify whether SMS programs implemented before the final rule would be automatically recognized as complying with the final requirements.

To facilitate maximum flexibility and scalability, the FAA does not propose to mandate a one-size-fits-all implementation approach. A certificate holder can phase implementation, either by SMS component or by movement versus non-movement area.

The FAA agrees that additional time is needed to facilitate the effective development and implementation of SMS. This proposal would require submission of the implementation plan within 12 months of the effective date of a final rule and submission of the SMS manual and/or ACM update within 24 months of the effective date of a final rule. The FAA believes that 12 months to develop an implementation plan and 24 months to develop and submit the SMS manual and/or ACM update is an acceptable length of time based on lessons learned from the pilot studies. In developing these documents, certificate holders will benefit from the experience of the pilot study airports. Similarly, the FAA plans to incorporate those experiences into advisory circular guidance, including templates for development of an implementation plan.

The FAA encourages voluntary implementation of SMS prior to the establishment of the requirements in a potential final rule. In creating these programs, the FAA encourages each certificate holder to establish flexible programs and processes that would allow it to make changes if its program differs from the requirements in a final rule. Additionally, the proposed implementation deadlines would apply to each certificate holder regardless of whether it has a pre-existing program or not. Therefore, a certificate holder with a voluntary SMS program would have the same 24 months to come into compliance with any differences between its program and the requirements of a final rule. The certificate holder would provide the FAA with an implementation plan identifying the gaps between its existing program and the final requirements and timelines for implementing processes or changes to close those gaps within the 24 months.

The FAA anticipates that a certificate holder's SMS will continually evolve over time based on lessons learned and best practices. Therefore, the certificate holder may find it necessary to amend its implementation plan or SMS manual over time.

D. Implementation Plan Approval and Inspector Authority

The NPRM proposed to require a certificate holder to submit an implementation plan describing how it would meet the SMS requirements and a schedule for implementing SMS components and elements. The proposal called for the FAA to accept the certificate holder's implementation plan.

One association requested inclusion of regulatory provisions for FAA review and feedback on the implementation plan, SMS manual, and ACM update. Also, related to implementation plan review, one certificate holder questioned the role of the FAA inspector in verifying completion of the implementation plan and whether the inspector would have authority to amend or alter the implementation plan after its approval.

The intent of an implementation plan is for the certificate holder to identify its plan for implementing SMS within the applicable areas and map its schedule for implementing the SMS requirements. While the FAA originally proposed accepting the implementation plan, the FAA now proposes to approve submitted implementation plans. This approval is consistent with the FAA's part 121 SMS rule and would provide certificate holders with feedback earlier in the development of SMS programs.

While the FAA originally planned to include examples of implementation plan content in advisory circular guidance, the FAA has chosen to enhance the rule text regarding the implementation plan submission, incorporating minimum details the FAA expects when a certificate holder submits an implementation plan. These details correspond to the key requirements of SMS that a certificate holder should be considering early in the implementation process. Developing a plan for these details would allow a certificate holder to adequately plan for requirements that may present time constraints and allow the certificate holder to meet implementation deadlines.

The FAA does not agree that timelines for feedback should be incorporated into regulatory language. Based on the preferred alternative and new proposed approach for approving implementation plans, the FAA would need to review and approve approximately 268 implementation plans. The Regional Airports Division Offices have experience with reviewing and approving large-scale changes to certificate holder documents, including the ACM, from past rulemaking actions. The FAA would handle these approvals in a timely manner in each Regional Airports Division Office.

The FAA would review implementation plans using a "first-in-first-out" approach. However, the FAA recognizes that some certificate holders may choose to wait until the deadline to submit implementation plans for approval. If the majority of implementation plans were submitted near the deadline, the FAA may then switch to a more risk-based approach for approval, reviewing submissions from certificate holders with the largest number of passenger enplanements or annual operations first. To ensure consistency in these approvals, the FAA intends to provide guidance in its Advisory Circulars and training to Regional Airports Division Offices on the review of the implementation plans.

The FAA would review an implementation plan to verify that the certificate holder identified its timeline for complying with each requirement and defined its methods for compliance. A certificated airport could proceed with development and implementation of its SMS while its implementation plan is under FAA review.

During the periodic inspection, inspectors would verify that the certificate holder continues to comply with the unique deadlines approved by the FAA. As more thoroughly discussed in later sections, an inspector would develop the inspection checklist based on the unique characteristics of the certificate holder's SMS, operations, and past compliance.

The NPRM also proposed that the FAA would approve the certificate holder's SMS manual if it chose to develop a manual separate from the ACM. Similar to the SNPRM's proposal to approve instead of accept the implementation plan, the FAA proposes to accept the SMS manual instead of approve it. Airports that participated in the SMS pilot studies found it necessary to update SMS manuals numerous times as they developed best practices through implementation. Therefore, by the FAA accepting the SMS manual, certificate holders would have greater flexibility adapting to lessons learned without resubmitting the SMS manual for approval. The SNPRM proposes that for a certificate holder choosing to maintain an SMS manual, the certificate holder would be required to submit any changes made to the SMS manual annually, consistent with its inspection schedule. This new proposed requirement would ensure that the FAA's copy of the SMS manual is current and available for the inspector to review before the certificate holder's annual inspection.

The FAA would continue to approve the ACM and its updates. For a certificate holder using an SMS manual, the certificate holder would cross-reference the SMS requirements in its FAA-approved ACM. Any changes to references in the ACM would require submittal to the FAA for approval. However, if the SMS manual changes do not affect the ACM cross-references, there would be no need to resubmit the

ACM pages for FAA-approval. If the certificate holder chooses to document the SMS within the ACM instead of a separate SMS manual, it would not have the flexibility afforded by the SMS manual. Changes would need to be submitted to the FAA for approval. Once the FAA accepts the certificate holder's SMS manual and/or approves ACM updates detailing the certificate holder's SMS, that document would be the primary means of complying with the SMS requirements under the proposed rule, not the implementation plan. The implementation plan serves as a tool to help the certificate holder develop and implement the various components and elements of SMS within the prescribed and/or approved deadlines. Once SMS is completely implemented, the implementation plan becomes obsolete. The FAA would not use the implementation plan as a compliance yardstick.

Certificate holders would have the opportunity to submit amendments to implementation plans, with review and approval being the responsibility of the Regional Airports Division Offices.

E. Non-Movement Area

The FAA received numerous comments regarding the non-movement area which can be generally categorized as follows: Definition, applicability, and control.

Based on findings from the pilot studies, the FAA proposed extending SMS requirements to the non-movement area of the airport. Since the term non-movement area was not previously defined in part 139, the NPRM included a proposed definition that defined the non-movement area as the area, other than that described as the movement area, used for the loading, unloading, parking, and movement of aircraft on the airside of the airport (including without limitation ramps, apron areas, and on-airport fuel farms).

Five certificate holders questioned the FAA's proposed definition. One certificate holder stated that the proposed definition did not align with existing definitions and could lead to confusion. The certificate holder recommended the FAA align the definition with the current definition for air operations areas. Two certificate holders requested the FAA clarify in the final rule that the non-movement area does not include or apply to landside operations.

Two certificate holders sought clarification on the areas identified in the definition and identified inconsistencies within the NPRM. Two other certificate holders requested the FAA exclude certain areas from the definition, including military and general aviation leaseholds and fuel farms. One of those certificate holders stated that joint-use airports already have safety systems in place to address safety issues and operational concerns, and lease provisions prohibit a certificate holder from imposing SMS within the military leasehold. Two certificate holders stated that fuel farms should not be included in a final rule because they are typically a contracted service and are already subject to regulation by DOT and local authorities.

The FAA has concluded the proposed definition is consistent with existing guidance on distinguishing airport areas based on whether aircraft are subject to air traffic control. The FAA also determined the air operations area definition identified in 14 CFR 153.3 should not replace the proposed non-movement area definition since this term is associated with security-related issues, rather than operational safety issues.

The FAA previously responded to issues regarding applicability to joint-use and general aviation areas, ramps, and bag-makeup areas in its Responses to Clarifying Questions. As many of these same issues were repeated in comments to the NPRM, a summary of those responses and their applicability to the SNPRM follows:

- The proposed rule does not apply to military facilities at joint-use airports, but the certificate holder could invite the military to participate in SMS activities.
- The proposed rule does not require airport tenants to have a separate SMS; it would be applicable to certificate holders of a part 139 AOC only.
- The definition applies to the entire non-movement area regardless of lease arrangements. The proposed rule includes broad requirements intended to increase flexibility to implement an SMS for a certificate holder's unique operating environment.
- A certificate holder's SMS would apply to any safety issues including employee safety, ground safety, vehicle safety, and passenger safety to the extent that they are related to aircraft operations.
- The definition for non-movement area does not include the interior of hangars.

Regarding general aviation areas of the airport, the proposed rule's requirements would give flexibility to each certificate holder to scale the implementation to its unique operating environment. A certificate holder would need to ensure that individuals authorized to access the movement and non-movement areas are aware of, and have the opportunity to report hazards to, the certificate holder's hazard reporting system. Many certificate holders may find it necessary to update airport rules and regulations, revise clauses in lease agreements, and renegotiate lease agreements where appropriate to have airport tenants participate in the airport's SMS. Therefore, while not directly applicable to fixed-base operators (FBOs), a certificate holder may need to work with tenants such as FBOs to ensure the tenants' employees authorized to access these areas are aware of the airport's hazard reporting system.

Similarly, if bag make-up areas are located outside the landside facilities in proximity to air carrier operations, the certificate holder would need to assure implementation of relevant portions of this proposed requirement, like awareness of the hazard reporting system, for individuals working in the external bag make-up area.

As for on-airport fuel farms, § 139.321(b)–(g) currently prescribe requirements applicable to fuel farms for things like inspections and training. Therefore, it would be a natural progression to implement relevant portions of SMS within the fuel farm environment.

Over 25 commenters, including certificate holders and industry associations, disagreed with or questioned applying SMS to the non-movement area. The certificate holders stated that applicability to these areas would be costly and require time to revise standard leases, rules, regulations, and minimum standards. Further, complex geometry, lease agreements, and operational agreements make managing the non-movement area airport-centric. Commenters contended the FAA does not have the time or experience to become familiar with each airport's non-movement areas to judge compliance. One industry association believed that inclusion of the non-movement area without regard to airport-specific considerations undermines the goals of scalability and flexibility. Another industry association and certificate holder believed that more study and guidance is needed before the FAA applies SMS to the non-movement area. These commenters further questioned applicability when a tenant or leaseholder is required to implement SMS under other FAA regulations.

The FAA disagrees with the commenters' issues regarding the applicability of SMS requirements to the non-movement area. The pilot studies found, based on reports from numerous participating airports, that it was difficult to apply SMS concepts to only the movement area because aircraft and airside personnel routinely flow between movement and non-movement areas.

The FAA also identified a large number of safety accidents and incidents occurring in the non-movement area. Analysis of these accidents and incidents indicates that safety in the non-movement area is a significant concern. The proactive approach to hazard identification and analysis of accidents, incidents, or other reported or collected data at each individual airport through an SMS would likely reduce these incidents. The FAA believes there are significant benefits of applying safety management principles to areas not previously regulated under part 139.

While commenters expressed concerns regarding the complexity of operations within the non-movement areas and the FAA's "inexperience" in these areas, the FAA does not propose specific technical requirements in the non-movement area. Instead, the FAA plans to learn from certificate holders as they implement and maintain SMS. Over time, the FAA expects certificate holders and inspectors to share lessons learned or best practices that will then be reported nationally. Similarly, the FAA expects certificate holders to consult with the FAA if they find trends or issues that require a systematic fix.

The FAA is committed to an interoperable approach to SMS and plans to take numerous steps to avoid duplication and enhance cooperation and reporting between the SMS efforts. In addition to providing advisory circular guidance, the FAA has included similar language regarding interoperability and duplication of hazard reporting in the *Safety Management Systems for Domestic, Flag, and Supplemental Operations Certificate Holders (Part 121 SMS)* final rule [80 FR 1308 (January 8, 2015)[13]].

The FAA disagrees with the commenters' request for stronger language regarding landside operations. The statutory authority supporting part 139 limits the agency's purview to issuing certificates and minimum safety standards for airports receiving certain passenger carrying operations. The agency's past and current standards apply minimum safety standards for those areas on an airport where passenger-carrying operations are conducted. Accidents or incidents within the terminal environment have minimal impact on the safety of passenger-carrying operations. Moreover, local and state safety codes and regulations would typically cover issues found within the landside environment.

Several commenters, including three associations and nine certificate holders, argued that certificate holders lack sufficient authority and control to impose SMS requirements on airport tenants operating in the non-movement area. These commenters further noted difficulty due to the variety of lease agreements, clauses, and terms. One certificate holder contended that most airports, including itself, do not have personnel or expertise to oversee safety in the non-movement area. Another certificate holder recommended the final rule recognize the uniqueness of the non-movement area and provide latitude based on the activities that occur within the non-movement area, the level of control that the certificate holder has over those activities, and the extent to which access is within the tenant's control. Alternatively, one certificate holder requested the FAA apply or impose the proposed SMS requirements on tenants or exclusive leaseholds and allow the certificate holders to delegate the proposed requirements for shared leaseholds.

One association opined that, in the past, certificate holders have retained some oversight over tenant operations in the non-movement area, but that the NPRM pushed certificate holders to assume a primary role for safety. If that is the expectation, the association strongly disagreed with FAA's vision for SMS in the non-movement area.

Finally, a certificate holder with multiple part 139 airports contended that it would need to renegotiate over 1,500 lease agreements, and that even with renegotiations, it still would not possess the authority needed to fully implement SMS in the non-movement area.

The FAA disagrees with the comments that certificate holders lack control in the non-movement area of their airports. The FAA also disagrees with the request to directly apply these proposed airport SMS requirements on airport tenants. Part 139 applies only to certificated airports. While there may be instances where the certificate holders are not the same entity as the airport owner, airport owners who accept federal financial assistance (the vast majority of part 139 airports) must maintain sufficient rights and powers to operate the airport in accordance with grant assurances, which includes both movement and non-movement areas.

F. Accountable Executive

The NPRM proposed a requirement for the certificate holder to identify the accountable executive for the airport. Consistent with ICAO's definition of accountable executive, the FAA's proposed definition for accountable executive in the NPRM stated that an accountable executive means a single, identifiable person who, irrespective of other functions, has ultimate responsibility and accountability, on behalf of the certificate holder, for the implementation and maintenance of the certificate holder's SMS. The accountable executive would also have to have full control of the human and financial resources required to implement and maintain the certificate holder's SMS. The accountable executive would also have final authority over operations conducted under the certificate holder's AOC and have final responsibility for all safety issues.

The FAA acknowledged in the NPRM that it may be difficult for publicly-owned and operated airports in the U.S. to identify an accountable executive based on this definition and invited comments.

Twelve commenters, including two associations, nine certificate holders, and one consultant, believed the proposed definition is impractical and needs revision. One association summarized the variety of comments certificate holders had, stating that the definition needs to reflect the realities of U.S. airports where an airport director has managerial responsibilities but does not have final authority over airport operations. The commenter noted that these airports usually have a governing body, such as a Board of Commissioners or City Council, which has ultimate responsibility for operational and financial decisions. Therefore, the highest approving authority may not be one individual, as required by the proposed definition. Further, this association requested any final rule definition reflect that, at the majority of U.S. airports, no single manager has unilateral authority to direct actions by tenants and other non-airport employees.

Other alternative definitions proposed by the commenters included:

- Mirroring the part 121 SMS definition;
- Allowing certificate holders to designate an accountable organization structure instead of one executive;
- Redefining the position to account for airport managers who do not have complete financial control; and
- Allowing for designation of an SMS or Safety Manager because the airport

---

[13] Correction made to applicability date, see 80 FR 1584 (January 13, 2015).

manager may not have the time or ability to fulfill the obligations of the accountable executive position.

One certificate holder requested any final rule include a provision that the FAA does not intend to hold individuals, including the accountable executive, personally liable for safety infractions or violations of the SMS.

The proposed definition eliminates differences between the part 121 and part 139 definitions. The concept of an accountable executive conforms to industry and international safety standards for SMS. The accountable executive's role is to instill safety as a core organizational value and to ensure that SMS is properly implemented and maintained through the allocation of resources and tasks. By designating an accountable executive, responsibility for the certificate holder's overall safety performance is placed at a high level within the organization. The individual should have the authority to ensure that the SMS is implemented and effective. Traditionally, safety programs were housed within one division of the certificate holder's organization. Under a systems approach, the concepts of SMS need to permeate throughout the certificate holder's organization to ensure that all offices, employees, and tenants with responsibilities in the movement and non-movement areas understand their role in SMS.

However, the FAA appreciates the diversity of certificate holder organizations and agrees that the ICAO definition of accountable executive could present compliance and operational challenges for many publicly-owned and operated airports within the U.S. Therefore, the FAA proposes the revised definition in § 139.5 of this proposed rule.

In practice, the FAA anticipates that most certificate holders would designate an airport manager or airport director as the accountable executive. Accountability cannot be delegated; therefore, a lower-level manager or supervisor could not serve as the accountable executive.

The FAA does not intend to require the designation of additional positions to implement the daily operation of the SMS. Such designations should be left to the discretion of the certificate holder based on its unique operating environment and management structure. A certificate holder would have this flexibility in establishing its safety organizational structure as identified in proposed § 139.402(a). The safety organizational structure would identify the positions and offices within the certificate holder's organization that have responsibility for or play a role in the safety of airport operations. This includes the "chain of command" and the means by which airport employees report safety concerns, hazards, and other safety-related information.

G. Data Protection

The NPRM included numerous proposed requirements for certificate holders to develop and maintain documentation for hazard reporting, identification, and assessment. While the FAA did not propose a requirement for certificate holders to provide those documents to the agency, the certificate holder would maintain the documents for historical and trend analysis as part of its continuous improvement efforts.

Seventeen commenters, including certificate holders and associations, addressed issues of data protection posed by the proposed rule. Only one association, which represents trial attorneys, agreed with FAA's approach to hazard reporting. This association cautioned the FAA from making any changes, claiming that restrictions on the disclosure of safety data flies in the face of safety and only serves to protect and immunize business entities from responsibility in the event of negligence or wrong doing.

All other commenters believed that, without explicit data protections, persons not employed by the certificate holder would be reluctant to voluntarily share information or report hazards for fear of litigation or public perception if the data is released through state or local sunshine laws. Many commenters believed that, without protecting SMS-related data, certificate holders would not be able to establish effective confidential reporting systems. Commenters made numerous recommendations including:

- Make SMS data confidential.
- Protect data in a similar manner that air carriers are able to protect safety data, such as a data collected under the Flight Operational Quality Assurance Program (FOQA) or the Aviation Safety Action Program (ASAP).
- Protect SMS data using Security Sensitive Information (SSI) provisions.
- Allow redaction of data.
- Establish a national database to accept voluntary safety information from certificate holders and other stakeholders using protections under 49 U.S.C. § 40123 and 14 CFR part 193.
- Make SMS data exempt from disclosure under the Freedom of Information Act (FOIA) pursuant to 49 U.S.C. § 40123 and part 193.

One certificate holder disagreed with the FAA's claim that certificate holders are in the best position to work with state and local legislators to provide additional protection from data disclosure. That certificate holder believed it is an unreasonable burden on airports to seek legislative exceptions to public records laws and will result in a patchwork of legal protection throughout the U.S.

Another certificate holder sought clarification on how the FAA will evaluate the certificate holder's program if there is no requirement to submit data to the FAA and, if the FAA does take or copy the certificate holder's documents, how they will be protected from FOIA.

Section 44735 of title 49 of the United States Code specifically contemplates the protection of SMS data that is voluntarily submitted, such as reports, data, or other information produced or collected for purposes of developing and implementing an SMS, from FOIA disclosure by the FAA. It is important to note, however, such protection could not be afforded to SMS information that is required to be submitted to the FAA, or is kept to satisfy compliance with other regulatory requirements. For these reasons, the FAA is not proposing data reporting requirements for safety-related data created under an SMS (such as hazard reports, safety risk management documentation, or safety assurance documentation). As such, consistent with the authority in section 44735, there should be no implications under FOIA for that safety-related data. The FAA, through its inspectors, could review a certificate holder's documentation to ensure compliance with part 139, but the FAA generally would not take possession of those documents unless the inspector was investigating an issue of non-compliance.

To further clarify the extent of protection that may be afforded under section 44735, the FAA notes that any record or other documentation that is required to show compliance with other regulatory requirements would not be protected. Any information protected under the statute is only protected from release by the FAA. If the information is submitted or released by the certificate holder to another government entity, the protections of the statute are not binding on these other entities. Nor are these documents necessarily protected from discovery in civil litigation, although the certificate holder would be free to ask the court for whatever protections would be appropriate under the rules of the relevant jurisdiction.

The FAA acknowledges that most certificate holders are owned by a state, a subdivision of the state, or a local governmental body. These certificate holders are best situated to understand and comply with their applicable State laws. The FAA is uncertain whether any FOIA exceptions would preclude disclosure requirements under applicable state law. Any redaction of SMS data potentially required to be disclosed would be subject to applicable state law requirements and not established by the FAA.

The FAA also notes that data protection under SSI provisions is inapplicable and may be impermissible because those procedures are for information obtained or developed in the conduct of security activities as described in 49 CFR part 1520.

The FAA cannot speculate on how a third party would report to or share information with a certificate holder's SMS. This proposed rule does not require third parties to turn over SMS data to a certificate holder. However, the proposal would require a certificate holder to establish a confidential hazard reporting system and encourage hazard reporting by all persons accessing the movement and non-movement area. The FAA believes an SMS program could be structured in such a manner to realize safety benefits while limiting the public release of confidential third-party information. Use of third-party servers and de-identification of reporter information prior to receipt by the certificate holder could be solutions that would limit release, subject to applicable state law.

The FAA believes that individual certificate holders are best situated to review and resolve hazard reports related to their unique operating environment. As discussed in the FAA's Responses to Clarifying Questions, the FAA would use existing regulatory oversight processes to ensure that systemic or national compliance issues are reported when appropriate. FAA Order 5280.5C, *Airport Certification Program Handbook,* requires coordination with and oversight by the Airport Safety and Operations Division for airport certification inspection activities. In accordance with that order, inspection findings are recorded in national databases by inspectors and reviewed by the Airport Safety and Operations Division. Furthermore, enforcement activities by Regional Airports Division Offices are required to be coordinated with the Airport Safety and Operations Division.

The FAA is exploring methods to create a national reporting database for voluntary reporting of SMS data. The agency requests comments from industry on the types of data or other information certificated airports could provide under a national reporting database. This data could be used for system-wide analysis, the development or amendment of standards, and risk-based approach to targeted inspections.

H. Liability

An SMS is a formalized approach to managing safety and includes the establishment of many proactive processes and analyses, and the creation of documentation that can be used for decision-making and trend analysis. The NPRM did not expressly discuss potential liability under this new proactive approach.

Fourteen commenters, including ten certificate holders, two associations and one anonymous commenter, raised issues related to liability, noting that SMS-related processes and documentation will expose certificate holders to additional liability. Eight of those commenters went further to claim that there would be increased liability for airport management, especially for the accountable executive, under the proposed requirements. For example, one certificate holder contended compliance with the proposed SMS requirements could alter the airport's liability under the standard of care laws, which vary from state to state. That certificate holder also feared that decisions, safety risk matrices, and other processes and documentation could become evidence in litigation or the subject of litigation.

Other commenters, including three certificate holders and an association, questioned how a certificate holder's SRM processes could be used against the airport if there is an incident on the airport and it is found that the certificate holder did not act consistent with its own safety risk assessment under its SMS. Furthermore, one association believed there would be increased liability for the certificate holder and the accountable executive if the standards are not high enough or if the standards are not met.

Another association stated that acceptable level of "risk" as is established for SRM safety risk assessments, runs counter to U.S. tort principles and practice. The association further stated that, by identifying a hazard, an airport operator then has a duty to address that hazard promptly through mitigation measures. Furthermore, the commenter noted that although some airports that are owned by a state or municipal entity may be fully or partially protected from negligence claims through sovereign immunity, many, if not most, airports are subject to suit for negligence under applicable state law. Thus, once an airport is aware of a hazard, it is at risk for a negligence claim if injury or damage occurs as a result of that hazard.

Several commenters, including three certificate holders, an air carrier, and an association asserted that certificate holders lack sufficient control in the non-movement area, and that an SMS could result in a certificate holder being held legally responsible for personal injury or property damage resulting from hazards identified through the airport's SMS in areas not under its control. One association argued that airport leases or license agreements transfer a certain degree of control from the airport/landlord to the tenant/licensee. While an airport may retain a certain degree of control, the tenant typically has a certain degree of autonomy to run its operations within the leased area as it sees fit, subject to legal requirements. There may be times where a certificate holder identifies hazards in the leased area that are not a violation of any enforceable obligation of the tenant. In these cases, the airport will have limited recourse.

Commenters made a number of recommendations including:

- Commit to join industry groups in seeking modifications to federal law;
- Prohibit, by regulation, the testimony of FAA employees in litigation against certificate holders where standards of care is an issue; and
- Provide explicit protection of the certificate holder.

The FAA cannot speculate on potential litigation resulting from a potential accident at some point in the future, which would be fact-specific and subject to applicable law that varies throughout the U.S. However, the FAA does not intend for this proposed rule to create or modify state tort liability law or create a private right of action under federal or state law. The FAA does not agree with the assertion that SMS increases liability for an airport operator or its accountable executive. The availability of additional data and analysis for decision-making should support a certificate holder in potential litigation. Failure to take action on identified safety hazards, regardless of formal analysis under SMS, generally may increase litigation risk. Nevertheless, the FAA intends for SMS to assist certificate holders in uncovering and mitigating unsafe conditions or actions, thus decreasing a certificate holder's litigation risk. A certificate holder could effectively use SMS to reduce liability by promptly investigating identified hazards and risks, conducting a thorough analysis of hazards, and keeping accurate records.

Furthermore, the new proposed definition for accountable executive would clarify that the accountable executive would not be personally liable to the FAA, through either certificate action or civil penalty. Additionally, the FAA does not intend for the accountable executive to have personal liability to any third party; however, issues concerning such liability are controlled by state law, not the SMS regulations.

Finally, the FAA notes that the extent to which SMS data may be discoverable in litigation is subject to the state or federal law governing the litigation. The FAA believes the certificate holder is in the best position to understand and comply with its state's laws.

I. Training

In the NPRM, the FAA proposed requiring certificate holders to provide formal training to all employees and tenants with access to the movement and non-movement areas appropriately tailored to the individual's role in the airport's SMS. The FAA invited comment concerning the practical and economic implications of the proposal, or applying the requirement to all individuals with access to those areas.

Ten commenters, including four certificate holders, three associations, one air carrier, one individual and one consultant, identified inconsistencies and various interpretations of the proposal. These commenters noted that terms like employee, tenant, and personnel were used ambiguously throughout the proposal. Three commenters requested the FAA coordinate the terms and definitions in the two rulemaking proposals for part 139.[14] An association and certificate holder requested that the FAA define these terms.

Two certificate holders offered the following alternate interpretations of the proposal:

(1) The certificate holder is required to train only its employees;

(2) The certificate holder is required to train those personnel who are employed at the airport (regardless of the identity of the employer); or

(3) The certificate holder is required to train all individuals with access to the movement and non-movement areas of the airfield.

One certificate holder questioned whether the requirement applies to all individuals with access to the movement and non-movement areas or only those that have authority to drive in those areas. The certificate holder requested the FAA reconsider the timing of the training requirement, citing a 2-year cycle instead of annual training as being more consistent with airport security badging processes.

Another certificate holder questioned who is responsible for training under the proposed rule and whether the certificate holder is responsible for training all airport tenants.

An association recommended the FAA allow a certificate holder to assess who needs training on its airport, and whether training should be extended to all individuals accessing the movement and non-movement areas. The association believed this would allow certificate holders maximum scalability by tailoring their training program and costs to reflect their unique operating environment.

Another association requested the FAA provide more detail on what topics should be included in the training program, and how a certificate holder would best implement the requirement. Certificate holders and one association expressed concerns about the lack of expertise of staff to implement such a training program, the magnitude of a program that reached all individuals with access to these areas (not just airport employees), and the workload associated with developing and providing training. To decrease workload, one certificate holder requested the FAA develop a basic SMS training course for certificate holders which could be augmented by an airport-specific course.

Commenters also offered a number of recommendations for scope changes including:

- Training personnel with regular, recurring access to the airport only;
- Training employees with responsibilities outlined in the ACM only;
- Training certificate holder employees only; or
- Allowing train-the-trainer programs.

Associations representing air carriers and pilots expressed concern about the FAA's proposed training requirements in the non-movement area, questioning how flightcrew members of airline tenants would be able to comply based on dynamic scheduling. One association recommended flight crew training remain an airline responsibility. Another association rejected the notion of training individuals with access to the non-movement area, claiming that existing training requirements are sufficient.

One association recommended the FAA clarify timelines for training, suggesting that certificate holders begin training their managers and employees within 12 months of the FAA's approval of the SMS manual.

A consultant observed that training implies an increased level of liability, and that the FAA should instead require orientation. This orientation should focus on general safety training such as ramp markings, airport rules and regulations, hazard reporting, and accident and incident response and reporting.

Finally, a certificate holder requested the FAA not mandate recurrent training.

The NPRM proposed an SMS training requirement for all employees and tenants with access to the movement and non-movement areas of the airport. To maximize the potential for proactively identifying hazards, the intent was to ensure that individuals authorized access to the movement and non-movement area received training. This would create a broad training requirement, allowing certificate holders flexibility in how they trained persons with access to these areas. This flexibility included allowing train-the-trainer programs and training specific to the person's role in the SMS. This flexibility would allow certificate holders to provide orientation to the majority of persons accessing the non-movement and movement areas of hazard identification and reporting, rather than training on all of their SMS initiatives.

Commenters appear to have interpreted the proposed training requirement to be cumbersome, time consuming, and excessively costly. In light of comments and lessons learned from the pilot studies, the proposal in this SNPRM offers a two-pronged approach to training: (i) Comprehensive SMS training specific to the individual's role and responsibility in implementation and maintenance of the SMS and hazard awareness; and (ii) reporting awareness orientation for all other individuals with access to the movement and non-movement areas.

The FAA expects each certificate holder to provide training appropriately tailored to the person's role in the certificate holder's SMS. Persons with responsibilities for implementation or oversight of the certificate holder's SMS would be required to receive training specific to their roles and responsibilities. For example, those persons responsible for analyzing hazard reports to determine action should be properly trained in SRM and hazard assessment procedures. Individuals, including staff and/or managers, with responsibility for daily oversight of the SMS would be trained in all requirements of the SMS. Again, the certificate holder could use train-the-trainer formats where necessary.

---

[14] During the NPRM comment period, the FAA published the "Safety Enhancements, Certification of Airports" NPRM proposing updates to part 139. After reviewing comments, the FAA issued a final rule (78 FR 3311, January 16, 2013).

By clarifying this proposed requirement, the FAA anticipates the average pool of employees needing this training to be between 3 and 10 employees or managers per airport. The supplemental initial regulatory evaluation uses these estimates in the cost analysis. The FAA requests comments on whether these estimates are accurate as an average across all airports affected by this proposal. The FAA acknowledges that there may be certificate holders included in the preferred applicability alternative who have smaller staffs than these numbers take into account. In those environments, additional staff may not be necessary but rather, existing staff could assume these duties and responsibilities within their existing job roles. Thus, the FAA also requests comments on the job roles that would require this type of specific training.

For the remaining persons who have access to the movement and non-movement areas, a certificate holder could use a variety of means to provide hazard awareness and reporting orientation. For example, a certificate holder could develop a brochure or white paper for inclusion in the employee's indoctrination package, or add a reference to hazard identification and reporting to existing training programs, such as security or driver training.

The certificate holder would bear the cost of publishing this awareness material and keeping it updated. For persons employed by tenants, the certificate holder would be responsible for providing the materials to the tenants for distribution. Tenants, such as air carriers, caterers, fueling agents, and FBOs, all would potentially receive this information if their employees access the movement or non-movement areas. However, the certificate holder could choose to provide this material or briefings during badging or security training.

There should be minimal record keeping costs associated with this type of training/awareness orientation. The certificate holder would maintain training records for only those individuals receiving comprehensive SMS training. For hazard awareness and reporting orientation, the FAA anticipates the certificate holder would retain copies of materials provided and a distribution log detailing when the materials are provided to tenants. The certificate holder would not be required to maintain individual training records for hazard awareness and reporting orientation.

The FAA does not intend for the proposed requirement to apply to persons escorted by a trained individual. As for an air carrier's crewmember training, those individuals authorized to enter the movement and non-movement areas unescorted would receive training appropriate to their role; in this case, awareness of hazard identification and reporting procedures. The air carrier would then distribute the materials provided by the certificate holder.

While the NPRM did not explicitly propose recurrent training, the FAA envisions the need for a certificate holder to provide individuals with updated information, all in support of a positive safety culture. This proposal includes a requirement for recurrent training every other year. It also would require the update of publications for the hazard awareness orientation requirement on the same schedule.

This proposal also includes cross-references between the new proposed training requirement in § 139.402(d) and existing training references in § 139.303(e). It ensures consistent formatting with existing requirements in part 139.

J. AIP Eligibility

Sixteen certificate holders, two associations, and one consultant expressed concern that the proposal was not clear on how certificate holders should fund SMS development and implementation and whether federal financial assistance through the Airport Improvement Program (AIP) would be available for SMS-related items. If AIP funding is made available, commenters sought clarification on eligibility in general, and, specifically, regarding the purchase of software for hazard tracking, analysis, and reporting, as well as for SMS manual development.

One certificate holder pointed out that if AIP funds are made available and Congress fails to provide additional funding to the program, airports would be forced to comply using the same funds that are used to make improvements to airport infrastructure.

Four certificate holders requested the FAA delay a final rule until a dedicated funding source for initial and recurring costs related to SMS is found.

The FAA acknowledges that the NPRM was silent about AIP funding for development and implementation of the SMS requirements. The question of AIP eligibility is not relevant to an estimation of the cost of the proposed rule. The question of who pays involves an economic transfer, not a societal cost.

Compliance with part 139 is not dependent on AIP eligibility. However, the FAA understands the concerns expressed by the commenters. In August 2013, the FAA issued Program Guidance Letter 13–06, *Safety Management Systems (SMS),* which addressed similar issues in more detail. This guidance was later canceled when its contents were moved to the updated FAA Order 5100.38D, *Airport Improvement Program (AIP) Handbook.*[15] The following provides a general overview of AIP funding of SMS efforts. However, as with any question involving AIP funding, the airport sponsor must work directly with the local FAA Airports District Office (or Regional Airports Division Office in regions that do not have District Offices) in connection with questions about eligibility, justification, and availability of funds for specific efforts. There are rules associated with the types of funds, projects, and airports that can receive AIP funding. With that said, the FAA has committed to making some SMS-related costs eligible for federal financial assistance under AIP.

In general, the FAA has determined that reasonable costs incurred for development of an initial implementation plan and SMS manual are eligible for AIP planning grant funds. The portions of the SMS manual and implementation plan development that are within the control of the airport sponsor, through enforcement of the airport's published Rules and Regulations, Minimum Standards, or other existing controls, can be funded with AIP. AIP funds can help establish safety protocols that affect users of the airport, but AIP funds cannot be used to help users of the airport manage their own operations. Revising an ACM to include SMS requirements in the ACM would not be eligible for AIP funds.

SRM activities conducted under the certificate holder's SMS are considered a part of the airport's day-to-day activities. Because operational costs are not eligible under AIP, these ongoing activities and their incurred costs are not eligible. Recommendations from SRM activities, including mitigations to decrease risk, are not necessarily eligible because a recommendation may be wholly operational, or may involve work from ineligible entities (such as the FAA Air Traffic Organization or other FAA lines of business that have independent operational budgets).

It is possible that a SRM recommendation may be an allowable cost of an AIP-eligible capital project or may be independently eligible as an AIP capital project. In these cases, the cost would be part of the eligibility priority and justification requirements of the project type and airport size classification. For example, a certificate holder's SRM process recommends relocating a taxiway to eliminate a runway crossing hazard. In that case, because taxiway projects are already eligible under AIP, the taxiway project recommended through SRM will follow the existing published eligibility requirements for taxiway projects.

---

[15] Issued September 30, 2014 and available at *http://www.faa.gov/airports/aip/aip_handbook/*

Federally-obligated airports are already required under AIP Grant Assurance 19, Operation and Maintenance, to operate at all times in a safe and serviceable condition and in accordance with the minimum standards as may be required or prescribed by applicable federal, state, and local agencies for maintenance and operation. This includes identifying and mitigating hazards.

Therefore, although the FAA will continue to provide AIP funding for eligible capital improvements, it has always been (and remains) the certificate holder's responsibility to mitigate risks regardless of whether federal funding is available. Eligible and justified improvements are generally physical improvements to the configuration of airfield geometry (*e.g.*, physical layout of runways, taxiways, and appurtenant facilities), as well as associated signage, marking, and lighting. For AIP-eligible projects requiring hazard assessment led by the FAA, some of the associated costs for convening a panel may be included as allowable under an AIP grant.

The FAA's proposed requirements should not involve major expenditures in new systems, including hazard reporting systems. However, some airports that participated in the pilot studies used SMS software for development of the plan and SMS manual and/or for actual implementation of SMS. Therefore, the FAA will allow AIP funds to be used for the one-time (initial) acquisition of airport-owned software applications that are specifically designed to support airport SMS implementation. Other requirements and limitations may apply, which are outlined in the AIP Handbook.

However, experience from the pilot studies has also shown that smaller, less complex airports should be readily able to manage the associated steps, processes, and data using existing off-the-shelf, end-user spreadsheet or database software. Regardless of the airport's size and complexity, costs associated with staffing, training, or safety promotion are also not AIP eligible.

As always, when an airport sponsor requests AIP funding, the FAA is required to review the existing conditions, the available alternatives, and the criteria by which the sponsor has concluded that a particular solution is the preferred course of action. That is why early coordination with the local FAA Airports District Office or Regional Airports Division Office is crucial.

K. Interoperability

The FAA is engaged in numerous efforts to require and incorporate SMS concepts into industry and its own operations. The practice and results of these efforts appear to be meeting in the airport environment. For example, besides this proposed rule, the FAA recently published a final rule for air carriers operating under part 121, which also requires hazard reporting and proactive hazard assessment. See 80 FR 1306 (January, 8, 2015). Furthermore, the FAA's own internal efforts to incorporate formalized hazard assessment into many of its operations and approvals will impact part 139 certificate holders and part 121 air carriers. Recognizing the interoperability of these efforts would be important for the continued success of SMS, the FAA requested comment on the interaction between the proposed rule and potential future rulemakings.

The majority of commenters raised issues regarding interoperability and how all of the various SMS efforts and requirements will work together, avoiding duplication and conflict. These issues can be grouped into three themes:

1. Reporting of hazards, overlap of responsibility and duplication of efforts: Seven commenters, including five certificate holders, one association, and one air carrier, questioned which hazard reporting system should a person use to report an observed airport hazard when both an air carrier (or multiple carriers) and the certificate holder may have an interest. One commenter noted that air carriers also may be reluctant to share safety information with airports because of data protection issues. Additionally, reporting into two separate reporting systems and separate analyses would be a duplication of effort that is inconsistent with SMS philosophy.

2. Hazard assessments for hazards shared by multiple regulated entities: Twenty commenters, including fifteen certificate holders, three associations, one air carrier, and one anonymous commenter, questioned which entity has responsibility for performing the hazard assessment on shared hazards and by which rules the assessment is performed. One commenter noted there may be divergent interests among the entities as to how to mitigate a particular hazard. For example, an airport may not want to bear a costly mitigation when another possible mitigation may be more acceptable to it. The airport and air carrier could perform individual assessments, but that result would duplicate efforts and be contrary to cooperation between the entities, both of which are inconsistent with SMS philosophy. Additionally, the airport and the air carrier may have different methodologies for assessing risk (such as different risk matrices). One commenter also raised the issue of which risk matrix would be used and how to resolve disputes over which matrix to use (*e.g.*, different severity and likelihood categories and definitions).

Another commenter further questioned how the FAA's internal SMS efforts within the Air Traffic Organization, Office of Aviation Safety, and Office of Airports will interact with certificate holders. For example, one certificate holder believed that conflicts between the various efforts could be complex and unavoidable and stated that the FAA needs to address resolution including hierarchy and authority in the final rule.

3. Differing definitions and standards: Two commenters, including one certificate holder and one anonymous commenter, expressed concern regarding differing definitions and standards throughout the various SMS efforts. One certificate holder believed the definitions should be consistent across the agency so that everyone speaks the same language. Examples of inconsistent definitions include the terms hazard, risk, risk control, and risk mitigation. One commenter raised concerns that because each entity has the flexibility to set its own severity and likelihood categories and definitions, it will be difficult to understand what these different definitions mean.

With regard to reporting hazards and overlap of responsibility, the FAA has taken efforts to reduce conflict and duplication but acknowledges that some overlap may occur. Regardless of overlap, certificate holders would be expected to comply with the applicable SMS requirements. Certificate holders would address the hazards reported to them and also conduct SMS promotion activities to encourage reporting.

For example, an airline ramp worker identifies a safety issue in his work area on the ramp. The worker reports this issue to both the airport and airline's hazard reporting system. In this scenario, both the airport and the airline have a responsibility for reviewing the reported safety issue. However, their responsibility for analyzing and possibly mitigating the issue depends on who holds overarching responsibility for the issue and/or its mitigation. If it is something that only the airport can take action to prevent or mitigate, the airline would forward that information to the airport for action. Similarly, if only the airline could take action, the airport would forward the report to the airline.

While the FAA cannot regulate relationships between certificate holders and other entities, the FAA can include best practices and lessons learned to help foster an environment conducive to sharing hazard information across industry groups. Although there may be two separate regulations addressing SMS, the FAA encourages air carriers and airports to communicate with one another when hazards are identified through their respective SMS procedures and processes that may be addressed by the air carrier or airport. For example, if an air carrier's employee identifies a hazard on the movement area of the airport, the air carrier employee would likely report the hazard through the air carrier's SMS employee reporting system. Once reported, the FAA recommends that the air carrier notify the airport of the identified hazard so the airport is aware of the issue and may analyze the risk accordingly. In addition, the air carrier may also opt to analyze the risk of the hazard and determine if it warrants any sort of mitigation through the revision or further development of the air carrier's procedures. This type of communication would serve to ensure that hazards, whether unique to the air carrier, or more systemic to the airport, are being addressed effectively by all parties.

The FAA expects that information sharing will increase over time as entities become more familiar with SMS and its benefits. Furthermore, the FAA is continually evaluating the implementation of SMS and is prepared to address issues as they arise.

With regard to differing definitions and standards, the FAA harmonized definitions in the rules where possible. However, some definitions are different based on the different operating environments. Some definitions may evolve over time based on lessons learned.

This proposal harmonizes with the part 121 SMS rule definition for hazard and risk. These definitions would be added to § 139.5.

The definition for risk mitigation in this SNPRM does not harmonize with the part 121 risk control terminology. ICAO Annex 14 and the FAA Office of Airports' internal SMS policy use the term mitigate when discussing the fifth step of hazard assessment under SRM. The FAA has concluded the term mitigate is straightforward and aligns with other guidance certificate holders have received related to FAA SMS initiatives. To change terminology here runs the risk of confusion.

Relative to the separate standards for air carriers, the FAA notes that both SMS rules are structured in accordance with the ICAO SMS framework. However, the FAA recognizes that there are inherent differences in the operation of an airport and of an air carrier. Based on a review of these differences, the FAA determined that the rulemakings should proceed as separate projects.

A certificate holder may want to consult with its tenants, including air carriers, as it develops its implementation plan and SMS manual and/or ACM update. While not required to coordinate or incorporate each other's processes, the airport could benefit from the experiences of other entities that have already implemented SMS or other risk-based approaches.

The FAA continues to explore options to enhance interoperability within the airport environment. Technology solutions used by both the air carriers and airports could promote information sharing, enhanced communications, and provide cost savings. The FAA is open to suggestions from commenters on the use of existing systems to enhance interoperability.

L. FAA Oversight

The NPRM included a lengthy discussion on the FAA's role and oversight of certificate holders under the proposed SMS requirements. Emphasis was placed on the point that SMS is not a substitute for compliance with existing regulations or FAA oversight activities. The FAA provided examples of possible inspector activities to verify compliance with the requirements.

Fourteen commenters, including associations, certificate holders, and one consultant, commented on the FAA's oversight activities related to the proposal. Comments focused on three main areas: compliance and enforcement, inspections, and training.

Three associations and two certificate holders expressed concern about how the FAA would enforce compliance with the new SMS requirements and requested the FAA include measures or tools that a certificate holder or the FAA would use to ensure compliance with SMS requirements. While acknowledging that the FAA stated inspectors would not second guess certificate holder decisions, but would assess compliance with SMS-approved processes and procedures, one certificate holder requested the FAA include this language in the regulatory text. The other certificate holder expressed concern regarding the potential for "double jeopardy," whereby a violation of an airport's SMS procedures as detailed in the SMS manual or ACM could also result in a violation of existing part 139 requirements. An association wanted the FAA to define which FAA office has responsibility for compliance and oversight and suggested it be a headquarters function to ensure consistent enforcement. A consultant argued that any enforcement action is inconsistent with the SMS philosophy of a non-punitive approach to safety.

An SNPRM is not a place to establish compliance and enforcement policies and procedures, which must be able to be adapted as conditions dictate. Nevertheless, the FAA believes it would be helpful to discuss some general expectations about inspections in an SMS environment.

The FAA does not plan to initially alter its inspection methodology if an SMS rule is adopted. Inspectors would continue to review and conduct annual, surveillance, and special inspections of part 139 certificate holders to determine whether the certificate holder is complying with applicable statutory and regulatory requirements. The FAA agrees that adding SMS-related items to an inspection would add time. However, the FAA believes that SMS is a vital means to enhance safety into the future and is prepared to absorb those resource costs.

In general, seven commenters wanted more clarification on how an inspector's review of SMS documentation or processes would fit into the existing part 139 annual inspection. Three certificate holders questioned how inspectors would inspect for SMS-related items in an already budget- and time-restricted inspection environment and what items will be of interest during the inspection (like hazards and mitigations identified during SRM analyses) or whether the certificate holder is complying with its implementation plan. One association requested the FAA incorporate additional reviews to assist certificate holders instead of waiting until an airport's annual inspection.

Again, the FAA does not plan to immediately change its inspection or oversight process as a result of this revised proposal. Regional Airports Division Offices would maintain responsibility for conducting inspections and the Airport Safety and Operations Division at FAA

Headquarters would maintain national program oversight. An inspector would evaluate whether a certificate holder is implementing SMS in accordance with its approved implementation plan.

The FAA currently inspects using traditional surveillance methods which focus on determining regulatory compliance using direct inspections of a certificate holder's personnel, facilities, and responses. This type of surveillance provides a snapshot of compliance.

As stated earlier, SMS considers safety from a systematic perspective (*e.g.*, assessments and process-oriented inspections rather than standard technical checklist-driven inspections). The FAA envisions that airport inspections would change to a system-based approach to harmonize with the certificate holder's systematic approach under SMS; this would allow an inspector to focus on areas of greater risk.

Unlike traditional checklist-driven inspections, a systems-based approach would verify the certificate holder has processes in place to proactively identify hazards, mitigate risk, and address non-compliance issues. The FAA would evaluate whether the certificate holder has effective SMS policies, processes, and procedures to identify, analyze, and mitigate safety hazards and risks. Corrective actions for certificate holders in the future would not be limited to fixing discrepancies found but also fixing the processes that should have proactively identified the discrepancy before the FAA inspection.

The evolution to a systems-based approach would not happen overnight. The FAA envisions a gradual transition, but one that would not completely replace traditional oversight. The inspector would continue to verify compliance with existing part 139 technical standards, and these items would continue to be included on the inspection checklist. Under SMS, the inspector would also be responsible for inspecting the certificate holder's SMS policies, processes, and procedures.

Typically, the inspector would start by reviewing the certificate holder's Safety Assurance program since this component includes processes to verify the effectiveness of the certificate holder's SMS. Using the required elements of a certificate holder's Safety Assurance program, the inspector would review documents related to the certificate holder's safety performance to verify it is meeting its safety objectives and complying with its SMS manual and/or ACM. Similarly, the inspector could review submissions to the airport's hazard reporting system and verify that the certificate holder has analyzed the safety risk of hazards reported consistent with the issue reported. This level of assessment of the certificate holder's hazard reporting system and processes could be simply a spot-check.

The purpose of this review would not be to second guess the certificate holder's actions, but rather to ensure the certificate holder is following its own processes as documented in the SMS manual and/or ACM. The FAA could also review any trend analysis conducted by the certificate holder in an effort to determine whether the certificate holder is actively detecting root causes of safety issues. The inspector's review of this documentation is meant not only to find potential violations of standards but also to determine whether the certificate holder is taking appropriate action to evaluate the root cause of that non-compliance.

The inspector would also sample the certificate holder's SRM documentation. While not conducting this review to second-guess the certificate holder's actions, the inspector would evaluate whether the certificate holder is following the processes and procedures identified in its SMS manual and/or ACM and whether the certificate holder has implemented the mitigations identified. If during the review, the inspector found that the certificate holder had used its SRM processes to circumvent existing requirements under part 139, the FAA could look more extensively into the certificate holder's analysis because part 139 applies regardless of SRM processes. Avoiding part 139 requirements is not the purpose of the SRM program.

The inspector would sample training and communication documentation as required by the certificate holder's Safety Promotion program. The inspector would determine if the certificate holder is complying with its SMS manual and/or ACM with regards to its Safety Promotion program.

To verify compliance with the certificate holder's Safety Policy program, the inspector would verify that the certificate holder has a process in place to verify that the SMS manual and/or ACM is maintained and that information is kept up to date. If necessary, the inspector could validate information in these manuals to verify compliance.

If an inspector found discrepancies, the inspector could determine the need to conduct a more in-depth assessment of the certificate holder's processes and procedures for compliance. If the inspection uncovered a noncompliant condition that the certificate holder had previously identified and is in the process of analyzing that condition, the FAA could have ongoing involvement in the analysis to ensure the non-compliant condition is corrected and mitigations are put in place to prevent a reoccurrence.

Prior to inspection, the inspector could review the airport's inspection history to develop a risk profile specific to the airport. Using templates in FAA Order 5280.5, the inspector would develop an inspection checklist unique to the airport for that year's inspection. The checklist would be based on existing part 139 technical requirements, past compliance history, national programmatic priorities, and any additional factors the inspector believes necessary. In each case, the inspector would tailor parts of the evaluation and checklist to the certificate holder's unique SMS processes and operations. Moreover, the inspector could continue to review the ACM, SMS manual, or other records to verify compliance, as is done today. The FAA does not believe clarification of inspection items or processes is appropriate for rule text.

In addition to developing templates for the inspection checklist, the FAA would also amend FAA Order 5280.5, Airport Certification Program Handbook, to provide guidance to inspectors on documenting their inspection findings. Inspectors would craft a detailed narrative of their inspection findings rather than short responses as are typical in traditional inspections. Inspectors would describe in detail what they did and what they found that constitutes non-compliance rather than listing the discrepancies and conditions. Detailed narratives would afford the FAA more specific data, information, and examples to use for programmatic and system-wide reviews and analyses.

The FAA expects a certificate holder's SMS to be implemented when it would submit its SMS manual and/or ACM update. During the inspection, the inspector would verify that the certificate holder is following its approved implementation plan, updated FAA-approved ACM, and SMS manual (where applicable).

While not including SMS review in the annual inspection until a certificate holder's compliance date, inspectors could still offer guidance and assistance to the certificate holder. In the past, regions have offered workshops to assist certificate holders with understanding, implementing, and reviewing new requirements or standards. The FAA would highly encourage certificate holders to discuss implementation with their inspector and submit drafts of their implementation plan for review before the final deadline for submission.

One association and five certificate holders commented on the FAA's timeline for training its inspectors on the implementation and oversight of the rule and how FAA plans to continuously train inspectors after implementation. One certificate holder requested the FAA ensure consistency in developing, writing, reviewing, and approving airport SMS documents through training programs. One association asked for the opportunity to be briefed and comment on the inspector training program.

Guidance and training would be provided to all regional inspectors on how to determine if a certificate holder's processes and documentation meets the regulatory requirement for SMS. Furthermore, inspectors could always request additional information or policy guidance from the Airport Safety and Operations Division. If this proposed rule becomes effective, the FAA intends to include SMS in recurrent inspector training and would look for ways to be transparent and include industry input regarding training.

M. Safety Risk Management (SRM)

The NPRM included a requirement for certificate holders to establish a systematic process for analyzing hazards and their risks using a standard five-step process and standard documentation and record retention requirements. The NPRM clarified the use of the five-step process and provided examples for means of compliance. While the NPRM did not propose to require use of a predictive risk matrix for hazard assessment, it suggested its use through example.

One commenter questioned whether a certificate holder could deviate from the FAA's proposed five-step process.

Ten commenters, including one association, seven certificate holders, one consultant, and one anonymous commenter, raised concerns regarding the predictive risk matrix. However, there was no consensus within these comments regarding the use of predictive risk matrices. Several certificate holders wanted the FAA to require a standard predictive risk matrix, while others believed certificate holders should have the flexibility to establish their own.

Several commenters, including an association and certificate holders, shared the concern that the establishment and use of a predictive risk matrix increases liability. The association wanted the FAA to explicitly state that predictive risk matrices are unique to each certificate holder and should be treated as confidential.

The NPRM proposed minimum requirements for SRM, including establishing a systematic process to analyze hazards and their associated risks through a standard five-step process. Those five steps include (1) describing the system; (2) identifying hazards; (3) analyzing the risk of identified hazards and/or proposed mitigations; (4) assessing the level of risk associated with identified hazards; and, (5) mitigating the risks of identified hazards, when appropriate. As stated in the NPRM, these five steps represent the minimum requirements for this element of SRM. A certificate holder is not precluded from developing additional steps to facilitate its identification, analysis, and mitigation of hazards and risk. However, the certificate holder would need to incorporate at least these five steps at a minimum in its SRM processes.

The NPRM did not include a requirement to use a predictive risk matrix as part of the SRM process. The preamble suggested a risk matrix as an effective method to analyze and prioritize risk based on the likelihood and severity of a hazard's consequence. Although the FAA believes that the use of a predictive risk matrix meets the rule requirements, this proposed rule does not require its use. Each certificate holder would have flexibility and scalability to perform hazard assessments in a manner suitable to its unique operating environment. Furthermore, as stated in FAA's Responses to Clarifying Questions, to properly analyze the risk of identified hazards, a certificate holder would need to define its levels of likelihood, severity, and risk with which it is comfortable. The FAA intends to include examples of risk matrices in guidance materials.

The FAA acknowledges that not requiring the use of a specific risk matrix and standard severity and likelihood definitions may result in various risk matrices being utilized by certificate holders. The FAA believes this issue is outweighed by the benefits associated with maximizing flexibility and scalability to address these issues as each certificate holder chooses.

Regarding documentation and record keeping, a consultant requested the FAA develop a standardized template to document hazard assessment findings. One certificate holder requested the FAA revise its SRM-related records retention policy. That certificate holder contended any final rule should include 24 months instead of 36 months, claiming that the lesser is consistent with existing record retention requirements under part 139.

Again, the FAA acknowledges that not requiring the use of a standardized template for documenting SRM processes may result in varying SRM documents. The FAA believes this issue is outweighed by the benefits associated with maximizing flexibility and scalability to address this issue as each certificate holder chooses. However, the FAA intends to include a sample template for SRM documentation in guidance materials.

While the FAA recognizes that most existing part 139 record retention requirements are between 12 and 24 months, the FAA believes a longer retention is necessary for trend analysis to gain lessons learned, and for continual improvement under the certificate holder's SMS. The FAA proposed in the NPRM a requirement for the certificate holder to establish a system for identifying safety hazards. After further consideration, the FAA believes the term hazard is confusing and does not adequately address the genesis of the requirement. Each certificate holder and individual operating on the airport could have vastly different definitions of what constitutes a hazard, and such differences could limit what is identified. Under this proposed requirement, the FAA expects the certificate holder to have a system that proactively identifies issues that could lead to unsafe conditions within the movement and non-movement areas of the airport. Therefore, the FAA is proposing in § 139.402(b)(1) to require a certificate holder to establish a system for identifying operational safety issues.

N. Acceptable Level of Safety

The NPRM proposed that a certificate holder would establish and maintain safety objectives and an acceptable level of safety under the certificate holder's Safety Policy. However, the preamble did little to elaborate on the proposed requirement other than how to establish safety objectives.

Five commenters, including one association, three certificate holders, and one consultant, questioned the proposed requirement to establish an acceptable level of safety. One certificate holder wanted more clarification on how the FAA would ensure consistency throughout the industry (*e.g.,* to peg one airport against another) and questioned whether the different levels of acceptable risk would expose certificate holders to additional liability. Two certificate holders and one association wanted clarification of (or a definition of) acceptable levels of safety or how they are established, and on liability associated with defining an acceptable level of safety.

The FAA agrees with the commenters. The FAA no longer proposes to require establishment of an acceptable level of safety. The recently published ICAO Annex 19 instead requires member states to establish a State Safety Program for the management of safety in the state, in order to achieve an acceptable level of safety performance in civil aviation. Therefore, this requirement is applicable to the U.S. and the FAA, not to a certificate holder.

O. Safety Assurance

One certificate holder requested the FAA require a "Comprehensive Information System," an integrated information technology infrastructure, claiming that it serves as the foundation to support all of the SMS components and that without it, the SMS would be ineffective.

Neither the NPRM nor the SNPRM include a proposal requiring software. The FAA's proposal recognizes that certificate holders are in the best position to determine how they would meet the basic components and elements proposed. A certificate holder is not precluded from developing information management systems to support its SMS. The FAA would allow AIP funds to be used for the one-time (initial) acquisition of airport-owned software applications that are specifically designed to support airport SMS implementation. Other requirements may apply, which are outlined in the AIP Handbook.[16]

While not directly addressed through comments, the FAA proposes amending § 139.402(c)(1) to clarify safety performance monitoring. This change will also better link safety performance monitoring under Safety Assurance back to the safety objectives required under Safety Policy and § 139.402(a)(6). The FAA also proposes amending § 139.402(c)(3) to include compliance with part 139, subpart D requirements, in the regular report of safety information to the accountable executive.

P. Applicability to Other Airports and Out of Scope Issues

The proposal limited its applicability to holders of a part 139 AOC only. It appears, based on comments received, that some airport operators, owners, and associations confused the proposal with other SMS initiatives underway within the FAA and the FAA's Office of Airports. In addition, the FAA received comments on how it is currently applying SMS concepts to its own operations and approvals.

This proposed rule would not apply to airports that are not certificated under part 139. Further, comments received specific to the FAA's internal SMS efforts, including its publication of FAA Order 5200.11, are out of scope and have been forwarded for consideration under those efforts. As stated earlier, certificated airports may be affected by both this proposed rule and the FAA's internal SMS efforts, including proactive hazard assessment on approval actions before the agency. The FAA is developing these efforts to avoid duplication and enhance communication.

V. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995; current value is $155 million). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule. We suggest readers seeking greater detail read the full regulatory evaluation, a copy of which we have placed in the docket for this rulemaking.

In conducting these analyses, the FAA has determined that this proposed rule: (1) Has benefits that justify its costs, (2) is not an economically "significant regulatory action" as defined in section 3(f) of Executive Order 12866, (3) is "significant" as defined in DOT's Regulatory Policies and Procedures; (4) would have a significant economic impact on a substantial number of small entities; (5) would not create unnecessary obstacles to the foreign commerce of the United States; and (6) would not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

i. Total Benefits and Costs of This Rule

The FAA considered multiple alternatives for which part 139 certificate holders would be required to implement an airport SMS. The FAA analyzed the following alternatives:

- All part 139 airports;
- Airport operators holding a Class I AOC;
- Certificated international airports;
- Large, Medium, and Small hub airports and certificated airports with more than 100,000 total annual operations; and
- Large, Medium, and Small hub airports, certificated airports with more than 100,000 total annual operations, and certificated international airports.

Although an airport may belong in more than one grouping, the analysis did not double count the benefits and costs for any airport. The goal of analyzing these alternatives is to maximize safety benefits in the least burdensome manner. While the FAA is proposing a preferred alternative, each alternative presents various trade-offs of interest to the public.

The following table shows benefits and costs of the alternatives over 10 years.

---

[16] *See* Section V(J), AIP Eligibility, for further discussion.

COMPARISON OF COSTS AND BENEFITS OVER 10 YEARS

[2014 Dollars]

Base case	All ($)	Class I ($)	International ($)	L, M, S and >100K ops ($)	Preferred alternative: L, M, S, >100K ops, and international ($)
Benefits	$382,987,281	$368,096,671	$360,907,166	$356,128,301	$370,788,457
Costs	471,104,787	341,021,606	215,010,997	163,760,850	238,865,692
Net Benefits	−88,117,506	27,075,065	145,896,169	192,367,451	131,922,764
PV Benefits (7%)	233,282,770	224,210,033	219,830,291	216,919,352	225,850,869
PV Costs (7%)	307,842,595	223,584,687	141,796,001	108,819,973	157,496,312
PV Net Benefits (7%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557
PV Benefits (3%)	307,499,272	295,542,114	289,769,378	285,932,407	297,704,052
PV Costs (3%)	389,440,320	282,304,199	178,432,284	136,340,226	198,211,977
PV Net Benefits (3%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557

Mitigation Costs: Not quantified, estimates not included.
Given the range of mitigation actions possible, it is difficult to quantify potential benefits.

The estimated costs of this rule do not include the costs of mitigations that operators could incur as a result of conducting the risk analysis proposed in this rule. Given the range of mitigation actions possible, it is difficult to provide a quantitative estimate of both the costs and benefits of such mitigations. We anticipate that operators will only implement mitigations where benefits of doing so exceed the costs of the mitigations. In order for the estimated benefits to exceed the costs of the rule, the mitigation costs must be below $68.4 million over 10 years (discounted at 7%). The FAA requests comments on this assumption, as well as data regarding costs and benefits associated with any mitigations implemented through a voluntary SMS program.

ii. Who is Potentially Affected by This Rule?

Part 139 certificated airports

iii. Assumptions

- Discount rates—7% and 3% as required by the Office of Management and Budget.
- Period of analysis—2016 through 2025.
- The rule would take effect in 2016.
- The baseline value of a statistical life (VSL) for 2014 is $9.4 million.[17]
- VSL in future years were estimated to grow by 1.03 percent per year before discounting to present value.
- The value of a serious injury is $987,000.[18]
- The value of a minor injury is $28,200.[19]

iv. Benefits for the Preferred Alternative

The benefit estimates begin two years after implementation begins. The objective of SMS is to proactively manage safety, to identify potential hazards or risks, and to implement measures that mitigate those risks. The FAA envisions airports being able to use all of the components of SMS to enhance the airport's ability to identify safety issues and spot trends before they result in a near-miss, incident, or accident. Airports have already seen immediate benefits from increased communication and reporting that are all fundamental components of SMS. These efforts are expected to prevent accidents and incidents. These benefits are a result of identifying safety issues, spotting trends, implementing necessary safety mitigations, and communicating findings before they result in a near-miss, incident, or accident. Over the 10-year period of analysis, the potential benefits of the proposed rule for the preferred alternative would be $370.8 million ($225.9 million or $297.7 million in present value terms at 7% and 3%).

v. Costs for the Preferred Alternative

Base case	Preferred alternative: L, M, S, >100K ops, and international
Benefits	$370,788,457
Costs	238,865,692
Net Benefits	131,922,764
PV Benefits (7%)	225,850,869
PV Costs (7%)	157,496,312
PV Net Benefits (7%)	68,354,557
PV Benefits (3%)	297,704,052
PV Costs (3%)	198,211,977
PV Net Benefits (3%)	68,354,557

Mitigation Costs: Not quantified, estimates not included.

vi. Total Costs

Excluding any mitigation costs, which have not been estimated, the total costs of the SNPRM equal the sum of SMS manual/implementation plan development, staffing, equipment/material, training, update training records, and recording potential hazards over 10 years. The total cost of this rule for the preferred alternative is about $157.5 million in present value terms.

vii. Alternatives Considered

- All part 139 certificated airports—This alternative is not cost-beneficial.
- Class I airports—This alternative is not cost-beneficial.
- Certificated international airports—This alternative is cost-beneficial but does not capture all certificated airports with complex operations.
- Large, Medium, Small hub airports and certificated airports with total annual operations greater than 100,000—This alternative is cost-beneficial but does not harmonize with ICAO Annex 14.

---

[17] Office of the Secretary of Transportation Memorandum, "Treatment of the Value of Preventing Fatalities and Injuries in Preparing Economic Analyses—Revised Departmental Guidance 2015," May 2015.

[18] *Id.*

[19] *Id.*

COMPARISON OF COSTS AND BENEFITS OVER 10 YEARS

[2014 Dollars]

Base case	All ($)	Class I ($)	International ($)	L, M, S and >100K ops ($)	Preferred alternative: L, M, S, >100K ops, and international ($)
Benefits	$382,987,281	$368,096,671	$360,907,166	$356,128,301	$370,788,457
Costs	471,104,787	341,021,606	215,010,997	163,760,850	238,865,692
Net Benefits	−88,117,506	27,075,065	145,896,169	192,367,451	131,922,764
PV Benefits (7%)	233,282,770	224,210,033	219,830,291	216,919,352	225,850,869
PV Costs (7%)	307,842,595	223,584,687	141,796,001	108,819,973	157,496,312
PV Net Benefits (7%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557
PV Benefits (3%)	307,499,272	295,542,114	289,769,378	285,932,407	297,704,052
PV Costs (3%)	389,440,320	282,304,199	178,432,284	136,340,226	198,211,977
PV Net Benefits (3%)	−74,559,825	625,346	78,034,290	108,099,379	68,354,557

Mitigation Costs: Not quantified, estimates not included.
Given the range of mitigation actions possible, it is difficult to quantify potential benefits.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

The FAA identified at least 28 part 139 airports that meet the Small Business Administration definition of a small entity (which includes small governmental jurisdictions such as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000) out of the 268 part 139 airports considered in the preferred alternative. The FAA considers this a substantial number of small entities.

Of the 28 small entities, 25 are classified as small airports whereas the remaining 3 are large airports. In the regulatory evaluation, we estimated the costs over 10 years for all part 139 airports (we did not disaggregate costs by small airports and large airports). For this analysis, the FAA estimated the separate costs over 10 years for small airports and for large airports by taking an average across each of the two groups. Based on these 10-year cost estimates, the FAA projects the annual peak cost for small airports and for large airports at about $101 thousand; the FAA estimates the annualized costs over ten years at about $77 thousand and $81 thousand for small airports and large airports, respectively.[20] Because the relationship between the annual peak cost and the annualized cost for both airport groups suggests a moderately uniform cash flow stream, the FAA used the annualized cost to estimate the economic impact significance on small entities.

The FAA found the individual revenue for 22 airports out of the 28 small entities. The 2011 revenue ranges from about $97 thousand to $14.9 million.[21] Using the preceding information, the FAA estimates that their ratio of annualized costs to annual revenues is higher than 2 percent for 12 small airports. Therefore, the FAA performed a regulatory flexibility analysis for these 12 small entities.

Under section 603(b) of the RFA (as amended), each regulatory flexibility analysis is required to address the following points: (1) Reasons the agency considered the proposed rule, (2) the objectives and legal basis for the proposed rule, (3) a description of and an estimate of the number of small entities affected by the proposed rule (4) the reporting, recordkeeping, and other compliance requirements of the proposed rule, and (5) all Federal rules that may duplicate, overlap, or conflict with the proposed rule.

i. Reasons the FAA Considered the Proposed Rule

The FAA remains committed to continuously improving safety in air transportation. The FAA believes that an SMS can address potential safety gaps that are not completely eliminated through existing FAA regulations and technical operating standards. The certificate holder best understands its own operating environment and, therefore, is in the best position to address safety issues through improved management practices.

Both the NTSB and ICAO support SMS as a means to prevent future accidents and improve safety. The NTSB has cited organizational factors contributing to aviation accidents and has recommended SMS for several sectors of the aviation industry, including aircraft operators. The FAA has concluded those same organizational factors and benefits of SMS apply across the aviation industry, including airports. In 2001, ICAO adopted a standard in Annex 14 that all member states establish SMS requirements for airport operators hosting international operations. During the 2007 Universal Safety Audit Program evaluation of the U.S. implementation of ICAO standards and recommended practices, ICAO cited the FAA for failing to conform to the SMS standard and recommended practice in Annex 14. The FAA supports conformity of U.S. aviation safety regulations with ICAO standards and recommended practices.

---

[20] Annualized using a capital recovery factor of 0.14238, over 10 years, using a 7 percent rate of interest.

[21] Revenue data from Compliance Activity Tracking System (CATS) accessed on June 10, 2013 from *http://cats.airports.faa.gov.*

Moreover, in November 2007, the U.S. Government Accountability Office recommended the FAA develop a strategic plan to reduce accidents involving workers, passengers, and aircraft on airport ramps. The applicability of SMS to the non-movement area, including airport ramps, would help airports proactively identify and mitigate hazards; thereby, reducing the likelihood of future accidents and incidents.

ii. The Objectives and Legal Basis for the Proposed Rule

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

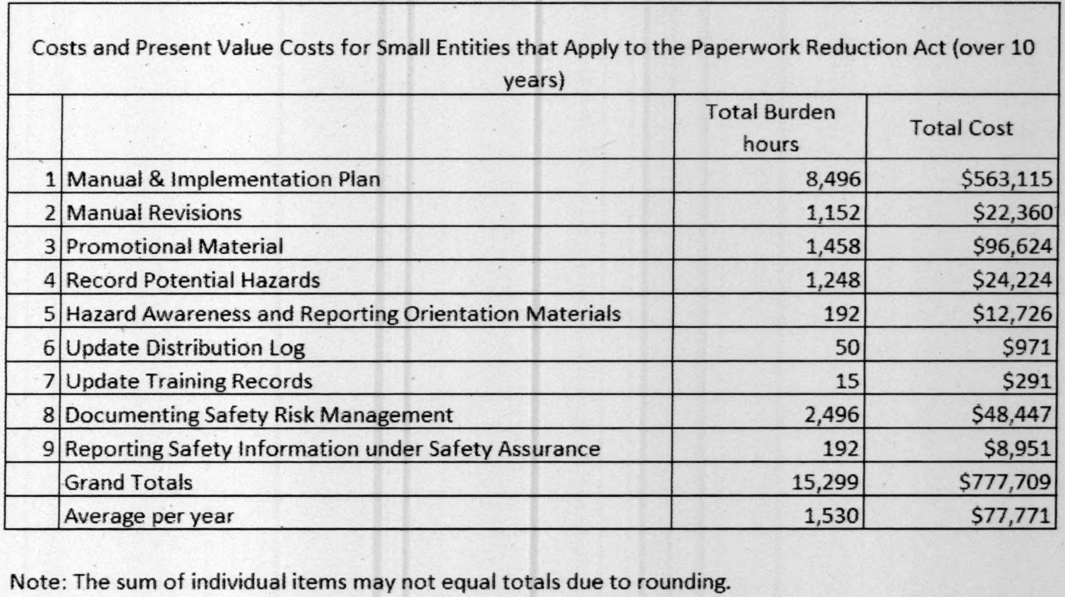
The FAA is proposing this rulemaking under the authority described in Subtitle VII, part A, subpart III, section 44706, "Airport operating certificates." Under that section, Congress charges the FAA with issuing AOCs that contain terms that the Administrator finds necessary to ensure safety in air transportation. This proposed rule is within the scope of that authority because it requires certain certificated airports to develop and maintain an SMS. The development and implementation of an SMS ensures safety in air transportation by assisting these airports in proactively identifying and mitigating safety hazards.

iii. Description of the Number of Small Entities Affected by the Proposed Rule

The FAA identified at least 28 part 139 airports that meet the SBA definition of a small entity. Their 2011 revenue[22] ranges from about $97 thousand to $14.9 million. Using the preceding information, the FAA estimates that their ratio of annualized costs to annual revenues is higher than 2 percent for 12 small airports.

iv. The Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA will submit a copy of these sections to the Office of Management and Budget (OMB) for its review. The following costs apply to the Paperwork Reduction Act.



Costs and Present Value Costs for Small Entities that Apply to the Paperwork Reduction Act (over 10 years)

		Total Burden hours	Total Cost
1	Manual & Implementation Plan	8,496	$563,115
2	Manual Revisions	1,152	$22,360
3	Promotional Material	1,458	$96,624
4	Record Potential Hazards	1,248	$24,224
5	Hazard Awareness and Reporting Orientation Materials	192	$12,726
6	Update Distribution Log	50	$971
7	Update Training Records	15	$291
8	Documenting Safety Risk Management	2,496	$48,447
9	Reporting Safety Information under Safety Assurance	192	$8,951
	Grand Totals	15,299	$777,709
	Average per year	1,530	$77,771

Note: The sum of individual items may not equal totals due to rounding.

v. All Federal Rules That may Duplicate, Overlap, or Conflict With the Proposed Rule

There may be some overlap between the proposed rule and existing Occupational Safety and Health Administration (OSHA) requirements, specifically record keeping and reporting requirements. However, the purpose and focus of this proposal is different. OSHA requirements focus on employee and workplace safety whereas proactive hazard mitigation and analysis under SMS focuses on safety in the movement and non-movement areas related to aircraft operations. Further, the FAA believes this proposed rule may have secondary benefits of improving employee safety.

vi. Other Considerations

a. Affordability Analysis

For the purpose of this analysis, the degree to which small entities can afford the cost of the rule is predicated on the availability of financial resources. Costs can be paid from existing assets such as cash, by borrowing, or through the provision of additional equity capital.

Commercial service airports that have accepted federal financial assistance under the AIP are required to report their financial information to the FAA. The FAA defines commercial service as airports with 2,500 or more enplanements in the preceding calendar year (see 49 U.S.C. 47102). Therefore, if a part 139 airport's enplanements fall below 2,500, its financial data would not be captured in the FAA's

---

[22] Accessed on June 10, 2013 at *http://cat.airports.faa.gov.*

Compliance Activity Tracking System (CATS) database.

One means of assessing affordability is by determining the ability of each small entity to meet its short-term obligations by looking at net income, working capital, and financial strength ratios. However, the FAA was unable to find this type of financial information for the affected entities and used an alternative way of analyzing affordability. The approach used by the FAA was to compare annual revenue (reported in the CATS database) with the annualized compliance costs. The ratio of annualized costs to annual revenues ranges from 0.54% to 79.6%. Thus, the FAA expects that some of these small entities may have difficulty affording this rule.

The costs used by the FAA are averages. Therefore, it is reasonable to expect that an airport could have less annualized costs than those depicted in this analysis. The proposed rule establishes broad requirements, affording maximum scalability and flexibility for airports to comply. Therefore, smaller airports have a variety of ways to comply with the broad requirements proposed under SMS. For example, to establish a confidential hazard reporting system, a smaller airport could simply establish drop-boxes around the airport and a schedule to check the boxes for submissions. Feedback could be given through memos posted in high traffic areas around the airport or near the drop-boxes.

The FAA intends to provide various templates in advisory circular guidance that smaller airports could use to establish their programs. The FAA anticipates offering a sample ACM update, SMS Manual, and templates for conducting SRM and reporting forms. A smaller airport would be able to easily modify these templates as necessary.

Smaller airports could also request federal financial assistance through AIP for costs incurred for development of the SMS Manual and implementation plan. The FAA also anticipates that certain costs associated with implementation of the SRM and Safety Assurance components may be AIP eligible.

It should be noted that multiple smaller airports in the pilot studies found ways to successfully develop and implement SMS within the constraints of their operations and budget. While these airports received AIP funding to conduct the studies, many established scalable programs that they are able to maintain without federal financial assistance.

Lastly, the proposed implementation plan requirements would allow small airports maximum flexibility in establishing their airport SMS. The certificate holder can phase implementation, either by SMS component or by movement versus non-movement area. Smaller airports would be able to spread the implementation costs over a longer period of time, thereby lessening the impact of this proposal.

b. Alternatives

The FAA considered the economic impacts on airports across multiple alternatives for which part 139 certificate holders would be required to implement an airport SMS:

- All Part 139 airports;
- Airport operators holding a Class I AOC;
- Certificated international airports;
- Large, medium, and small hub airports and certificated airports with more than 100,000 total annual operations; and
- Large, Medium, and Small hub airports, certificated airports with more than 100,000 total annual operations, and certificated international airports.

While the FAA is proposing the last alternative as its preferred alternative, each alternative presents various trade-offs of interest to the small entities (see the following table).

Comparison of Alternatives from the Perspective of Small Entities

	Alternative 1	Alternative 2	Alternative 3	Alternative 4	Alternative 5
	All part 139 (NPRM)	Class I	International	L, M, S and >100K ops	L, M, S, >100K ops, and International
Total number of small entities affected:	118	61	25	7	28
Is this a subtantial number of small entities?	Yes	Yes	Yes	Yes	Yes
Small entities for which this rule will have a significant impact?	12	8	11	1	12

As the table shows alternative 4 is the least burdensome for small entities. However, the FAA did not consider this to be an acceptable alternative because in addition to reducing the impact of the rule on small entities there were other competing goals including:

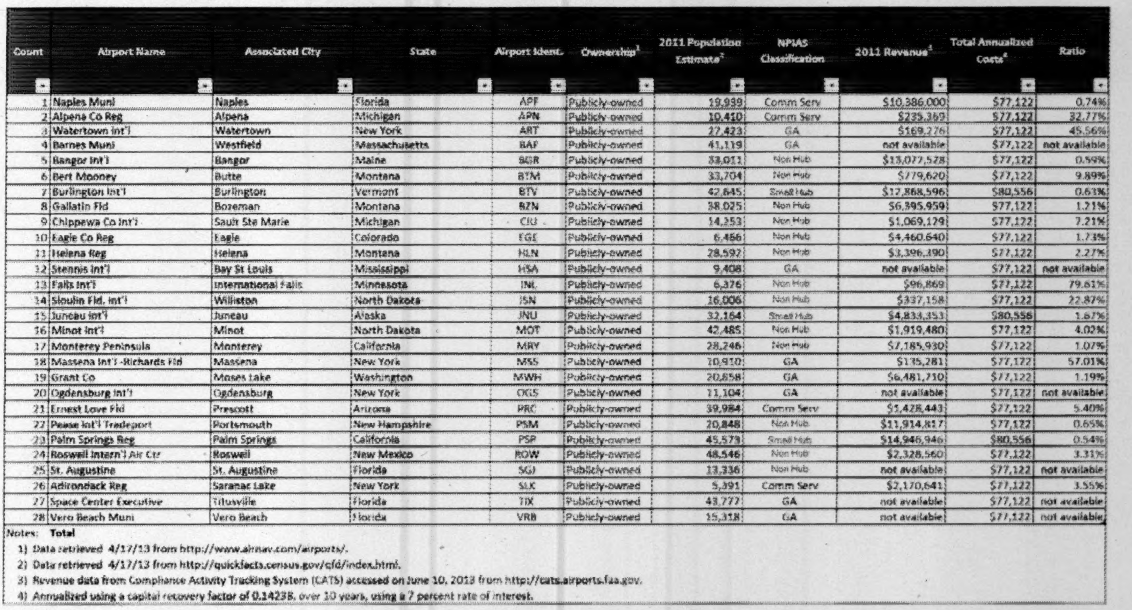
1. Choosing an alternative that provides high airport coverage; and

2. Harmonizing the alternative with the intent of international SMS standards. Alternative 5 in the table was the best alternative for meeting all such goals.

vii. Conclusion

This rule will have a significant economic impact on a substantial number of small entities. The FAA identified 12 small entities for which the rule will have a significant economic impact.

Annualized Cost as a Percentage of Revenue for Small part 139 Airports



Count	Airport Name	Associated City	State	Airport Ident.	Ownership[1]	2011 Population Estimate[2]	NPIAS Classification	2011 Revenue[3]	Total Annualized Costs[4]	Ratio
1	Naples Muni	Naples	Florida	APF	Publicly-owned	19,939	Comm Serv	$10,386,000	$77,122	0.74%
2	Alpena Co Reg	Alpena	Michigan	APN	Publicly-owned	10,410	Comm Serv	$235,369	$77,122	32.77%
3	Watertown Int'l	Watertown	New York	ART	Publicly-owned	27,423	GA	$169,276	$77,122	45.56%
4	Barnes Muni	Westfield	Massachusetts	BAF	Publicly-owned	41,119	GA	not available	$77,122	not available
5	Bangor Int'l	Bangor	Maine	BGR	Publicly-owned	33,011	Non Hub	$13,077,528	$77,122	0.59%
6	Bert Mooney	Butte	Montana	BTM	Publicly-owned	33,704	Non Hub	$779,620	$77,122	9.89%
7	Burlington Int'l	Burlington	Vermont	BTV	Publicly-owned	42,645	Small Hub	$12,868,596	$80,556	0.63%
8	Gallatin Fld	Bozeman	Montana	BZN	Publicly-owned	38,025	Non Hub	$6,395,959	$77,122	1.21%
9	Chippewa Co Int'l	Sault Ste Marie	Michigan	CIU	Publicly-owned	14,253	Non Hub	$1,069,129	$77,122	7.21%
10	Eagle Co Reg	Eagle	Colorado	EGE	Publicly-owned	6,466	Non Hub	$4,460,640	$77,122	1.73%
11	Helena Reg	Helena	Montana	HLN	Publicly-owned	28,592	Non Hub	$3,396,390	$77,122	2.27%
12	Stennis Int'l	Bay St Louis	Mississippi	HSA	Publicly-owned	9,408	GA	not available	$77,122	not available
13	Falls Int'l	International Falls	Minnesota	INL	Publicly-owned	6,376	Non Hub	$96,869	$77,122	79.61%
14	Sloulin Fld. Int'l	Williston	North Dakota	ISN	Publicly-owned	16,006	Non Hub	$337,158	$77,122	22.87%
15	Juneau Int'l	Juneau	Alaska	JNU	Publicly-owned	32,164	Small Hub	$4,833,353	$80,556	1.67%
16	Minot Int'l	Minot	North Dakota	MOT	Publicly-owned	42,485	Non Hub	$1,919,480	$77,122	4.02%
17	Monterey Peninsula	Monterey	California	MRY	Publicly-owned	28,246	Non Hub	$7,185,930	$77,122	1.07%
18	Massena Int'l -Richards Fld	Massena	New York	MSS	Publicly-owned	10,910	GA	$135,281	$77,172	57.01%
19	Grant Co	Moses Lake	Washington	MWH	Publicly-owned	20,858	GA	$6,481,710	$77,122	1.19%
20	Ogdensburg Int'l	Ogdensburg	New York	OGS	Publicly-owned	11,104	GA	not available	$77,172	not available
21	Ernest Love Fld	Prescott	Arizona	PRC	Publicly-owned	39,984	Comm Serv	$1,428,443	$77,122	5.40%
22	Pease Int'l Tradeport	Portsmouth	New Hampshire	PSM	Publicly-owned	20,848	Non Hub	$11,914,817	$77,122	0.65%
23	Palm Springs Reg	Palm Springs	California	PSP	Publicly-owned	45,573	Small Hub	$14,946,946	$80,556	0.54%
24	Roswell Intern'l Air Ctr	Roswell	New Mexico	ROW	Publicly-owned	48,546	Non Hub	$2,328,560	$77,122	3.31%
25	St. Augustine	St. Augustine	Florida	SGJ	Publicly-owned	13,336	Non Hub	not available	$77,122	not available
26	Adirondack Reg	Saranac Lake	New York	SLK	Publicly-owned	5,391	Comm Serv	$2,170,641	$77,122	3.55%
27	Space Center Executive	Titusville	Florida	TIX	Publicly-owned	43,777	GA	not available	$77,122	not available
28	Vero Beach Muni	Vero Beach	Florida	VRB	Publicly-owned	15,318	GA	not available	$77,122	not available

Notes: **Total**

1) Data retrieved 4/17/13 from http://www.airnav.com/airports/.
2) Data retrieved 4/17/13 from http://quickfacts.census.gov/qfd/index.html.
3) Revenue data from Compliance Activity Tracking System (CATS) accessed on June 10, 2013 from http://cats.airports.faa.gov.
4) Annualized using a capital recovery factor of 0.14238, over 10 years, using a 7 percent rate of interest.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that it has legitimate domestic objectives and uses ICAO international standards as its basis and, therefore, is in compliance with the Trade Agreements Act.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million.

This SNPRM would require certificate holders to implement an SMS to proactively identify, analyze, and mitigate safety issues in the movement and non-movement areas. It is not a significant regulatory action under the Unfunded Mandates Reform Act of 1995. Estimated costs do not exceed $155 million in any year of the 10-year analysis. Accordingly, the FAA has determined that this action does not have a substantial direct effect on the States. Moreover, this proposal would have low costs of compliance compared with the resources available to airports.

The provisions of this proposal are under existing statutory authority to regulate airports for aviation safety. The proposal would not alter the relationship between certificate holders and the FAA as established by law. Accordingly, there is no change in either the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

The FAA mailed a copy of the NPRM to each State government specifically inviting comment on federalism issues. The FAA received responses from two attorneys general, both indicating no comment. The FAA will mail a copy of the SNPRM to each state government specifically inviting comment on federalism implications.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

This action contains additional proposed amendments to the existing information collection requirements previously approved under OMB Control Number 2120–0675. As required by the Paperwork Reduction Act, the FAA has submitted these additional proposed information collection amendments to OMB for its review.

The NPRM contained estimates of the burden associated with the additional collection requirements proposed in that document. The FAA did not receive any comments specifically on these estimates. However, the FAA received comments on other areas in the initial regulatory evaluation that affect these estimates. These comments are discussed in the supplemental regulatory evaluation. In addition, these estimates have been adjusted in response to comments and due to changes in the proposed SMS requirements from the NPRM to this SNPRM (*e.g.*, applicability of the rule).

Title: Safety Management System for Certificated Airports.

Summary: The FAA proposes a rule to require certain certificate holders to establish an SMS for the entire airfield environment (including movement and non-movement areas) to improve safety at airports hosting air carrier operations. An SMS is a formalized approach to managing safety by developing an organization-wide safety policy, developing formal methods for identifying hazards, analyzing and mitigating risk, developing methods for ensuring continuous safety improvement, and creating organization-wide safety promotion strategies.

The proposal would require a certificate holder to submit an Implementation Plan within 12 months of the issuance of the final rule. The intent of the Implementation Plan is for a certificate holder to identify its plan for implementing SMS within the applicable areas, and map its schedule for implementing requirements.

In addition, a certificate holder would describe its means for complying with the proposed requirements by either developing an SMS Manual and updating its Airport Certification Manual (ACM) with cross-references, or documenting the SMS requirements directly in the ACM.

Finally, a certificate holder would be required to maintain records related to formalized hazard identification and analysis under Safety Risk Management, training records under Safety Promotion, and other Safety Promotion materials (also referred to as safety communications).

Use: While the implementation plan's main purpose is to guide a certificate holder's implementation, the plan also provides the basis for the FAA's oversight during the development and implementation phases. The FAA's review and approval of the implementation plan ensures that a certificate holder is given feedback early and before it may make significant capital improvements as part of its SMS development and implementation.

The ACM update and/or the SMS Manual establishes the foundation for an SMS. Like the implementation plan, the FAA would approve the ACM update. However, the FAA would accept the certificate holder's SMS Manual. Collection and analysis of safety data is an essential part of an SMS. Types of data to be collected, retention procedures, analysis processes, and organizational structures for review and evaluation would all be documented in either the ACM or the SMS Manual, with cross-references in the ACM. These records would be used by a certificate holder in the operation of its SMS and to facilitate continuous improvement through evaluation and monitoring. While the proposal does not require a certificate holder to submit these records to the FAA, it would be required to make these records available upon request.

Respondents: Application of these proposed requirements is limited to a certificated airport (i) classified as a Small, Medium, or Large hub airport in the NPIAS; (ii) identified as an international airport, or (iii) identified as having more than 100,000 total annual operations.

Frequency: The requirement to develop an implementation plan would be a one-time, initial occurrence. The requirement to create an SMS manual and/or update the ACM would be an initial occurrence. Updates to the SMS manual would occur on an as needed, ongoing basis, with annual submissions to the FAA. Other records would be created on an as needed, ongoing basis.

Burden Estimate:

a. Initial Burden—Certificate Holders—Draft Manual and Implementation Plan (§§ 139.401(d) and 139.403(a))

- Number of large airports [23]: 138.
- Number of small airports [24]: 130.
- Estimated time needed to create an SMS document and implementation plan per large airport: 508 hours per year for first two years.
- Estimated time needed to create an SMS document and implementation plan per small airport: 334 hours per year for first two years.
- Wage for SMS manager/coordinator: $66.28 per hour.

---

[23] For the purposes of this analysis, the FAA has defined "large airports" as Large, Medium, and Small hub airports.

[24] For the purposes of this analysis, the FAA has defined "small airports" as all certificated airports that are not Large, Medium, or Small hubs.

SMS Document for Large Airports

Year	Large airports	Hours/airport to create SMS document	Total hours	Total Cost
1	138	508.00	70,104.00	$4,646,493
2	138	508.00	70,104.00	$4,646,493
3				
4				
5				
6				
7				
8				
9				
10				
Total			140,208.00	$9,292,986
Average per year			14,020.80	$929,299

SMS Document for Small Airports

Year	Small airports	Hours/airport to create SMS document	Total hours	Total Cost
1	130	354.00	46,020.00	$3,050,206
2	130	354.00	46,020.00	$3,050,206
3				
4				
5				
6				
7				
8				
9				
10				
Total			92,040.00	$6,100,411
Average per year			9,204.00	$610,041

b. Initial Burden—FAA—Review Manual and Implementation Plan

- Number of large airports: 138.
- Number of small airports: 130.
- Estimated time needed to review an implementation plan per large airports: 16 hours in first year.
- Estimated time needed to review an implementation plan per small airport: 4 hours in first year.
- Estimated time needed to review an SMS document per airport: 8 hours in second year.
- Wage for inspector: $66.76 per hour.

Review of SMS document for Large Airports

Year	Large airports	Hours/airport to review SMS document	Total hours	Total Cost
1	138	16.00	2,208.00	$147,406
2	138	8.00	1,104.00	$73,703
3				
4				
5				
6				
7				
8				
9				
10				
Total			3,312.00	$221,109
Average per year			331.20	$22,111

Review of SMS document for Small Airports

Year	Small airports	Hours/airport to review SMS document	Total hours	Total Cost
1	130	4.00	520.00	$34,715
2	130	8.00	1,040.00	$69,430
3				
4				
5				
6				
7				
8				
9				
10				
Total			1,560.00	$104,146
Average per year			156.00	$10,415

c. Annual Burden—Certificate Holders

i. SMS Manual Revisions (§ 139.401(d)(2)(i))

- Number of airports: 268.
- Estimated time needed to revise SMS manual per airport: 12 hours per year starting in third year.
- Wage for clerical: $19.41 per hour.

SMS Manual Revisions

Year	Airports	Hours for manual revisions	Total hours	Total Cost
1	268			
2	268			
3	268	12.00	3,216.00	$62,423
4	268	12.00	3,216.00	$62,423
5	268	12.00	3,216.00	$62,423
6	268	12.00	3,216.00	$62,423
7	268	12.00	3,216.00	$62,423
8	268	12.00	3,216.00	$62,423
9	268	12.00	3,216.00	$62,423
10	268	12.00	3,216.00	$62,423
Total			25,728.00	$499,380
Average per year			2,572.80	$49,938

ii. Promotional Material (§ 139.402(d)(5))

- Number of airports: 268.
- Estimated time needed to create SMS promotional material per airport: 25.76 hours every other year starting in third year.
- Wage for SMS manager/coordinator: $66.28 per hour.

Promotional Material

Year	Airports	Hours/airport to create SMS promotional material	Total hours	Total Cost
1	268			
2	268			
3	268	31.83	8,531.68	$565,480
4	268		0.00	$0
5	268	31.83	8,531.68	$565,480
6	268		0.00	$0
7	268	31.83	8,531.68	$565,480
8	268		0.00	$0
9	268	31.83	8,531.68	$565,480
10	268		0.00	$0
Total			34,126.74	$2,261,920
Average per year			3412.673506	$226,192

iii. Recording Potential Hazards (§ 139.402(b)(1))

- Number of airports: 268.
- Estimated time needed to record potential hazard per airport: 15 minutes per year starting in third year.
- Estimated potential hazards per airport: 52 per year starting in third year.
- Wage for clerical: $19.41 per hour.

Recording Potential Hazards				
Year	Airports	Hours/airport to record potential hazards	Total hours	Total Cost
1	268		0.00	$0
2	268		0.00	$0
3	268	13.00	3,484.00	$67,624
4	268	13.00	3,484.00	$67,624
5	268	13.00	3,484.00	$67,624
6	268	13.00	3,484.00	$67,624
7	268	13.00	3,484.00	$67,624
8	268	13.00	3,484.00	$67,624
9	268	13.00	3,484.00	$67,624
10	268	13.00	3,484.00	$67,624
Total			27,872.00	$540,996
Average per year			2,787.20	$54,100

iv. Hazard Awareness and Reporting Orientation Materials (§ 139.402(d)(1))

- Number of airports: 268.
- Estimated time needed to develop hazard awareness orientation per airport: 8 hours in second year.
- Estimated time needed to update orientation per airport: 2 hours every other year starting in fourth year.
- Wage for SMS manager/coordinator: $66.28 per hour.

Hazard Awareness and Reporting Orientation Materials					
Year	Airports	Hours/airport to develop hazard awareness orientation	Hours/airport to update hazard awareness orientation	Total hours	Total Cost
1	268				
2	268	8.00		2,144.00	$142,104
3	268				
4	268		2.00	536.00	$35,526
5	268		0.00	0.00	$0
6	268		2.00	536.00	$35,526
7	268		0.00	0.00	$0
8	268		2.00	536.00	$35,526
9	268		0.00	0.00	$0
10	268		2.00	536.00	$35,526
Total			8.00	4,288.00	$284,209
Average per year			1.00	429.00	$28,421

v. Update Distribution Log for Hazard Awareness and Reporting Orientation Materials (§ 139.402(d)(2))

- Number of large airports: 138.
- Number of small airports: 130.
- Average number of tenants per large airport: 50.
- Average number of tenants per small airport: 10.
- Estimated time needed to update distribution log per large airport: 0.25 hours every other year starting in second year.
- Estimated time needed to update distribution log per small airport: 0.08 hours every other year starting in second year.
- Wage for clerical: $19.41 per hour.

Update Distribution Log for Large Airports

Year	Large Airports	Hours/airport to update distribution log	Total hours	Total Cost
1	138			
2	138	0.25	1,725.00	$33,482
3	138	0.00	0.00	$0
4	138	0.25	1,725.00	$33,482
5	138	0.00	0.00	$0
6	138	0.25	1,725.00	$33,482
7	138	0.00	0.00	$0
8	138	0.25	1,725.00	$33,482
9	138	0.00	0.00	$0
10	138	0.25	1,725.00	$33,482
Total			8,625.00	$167,411
Average per year			863.00	$16,741

Update Distribution Log for Small Airports

Year	Small Airports	Hours/airport to update distribution log	Total hours	Total Cost
1	130			
2	130	0.08	108.33	$2,103
3	130	0.00	0.00	$0
4	130	0.08	108.33	$2,103
5	130	0.00	0.00	$0
6	130	0.08	108.33	$2,103
7	130	0.00	0.00	$0
8	130	0.08	108.33	$2,103
9	130	0.00	0.00	$0
10	130	0.08	108.33	$2,103
Total			541.67	$10,514
Average per year			54.00	$1,051

vi. Update SMS Training Records (§ 139.402(d)(4))

- Number of large airports: 138.
- Number of small airports: 130.
- Estimated time needed to update training records per airport: 5 Minutes per record every other year starting in second year.
- Average number of employees per large airport: 10.
- Average number of employees per small airport: 3.
- Wage for clerical: $19.41 per hour.

Update Training Records for Large Airports				
Year	Large airports	Hours/airport to update training records	Total hours	Total Cost
1	138			
2	138	0.83	115.00	$2,232
3	138		0.00	$0
4	138	0.83	115.00	$2,232
5	138		0.00	$0
6	138	0.83	115.00	$2,232
7	138		0.00	$0
8	138	0.83	115.00	$2,232
9	138		0.00	$0
10	138	0.83	115.00	$2,232
Total			575.00	$11,161
Average per year			57.5	$1,116

Update Training Records for Small Airports				
Year	Small airports	Hours/airport to update training records	Total hours	Total Cost
1	130			
2	130	0.25	32.50	$631
3	130		0.00	$0
4	130	0.25	32.50	$631
5	130		0.00	$0
6	130	0.25	32.50	$631
7	130		0.00	$0
8	130	0.25	32.50	$631
9	130		0.00	$0
10	130	0.25	32.50	$631
Total			162.50	$3,154
Average per year			16.25	$315

vii. Documenting Safety Risk Management (§ 139.402(b)(3))

- Number of airports: 268.
- Estimated number of hazards documented per airport: 52 per year starting in third year.
- Estimated time needed to document SRM per airport: 0.5 hours per year starting in third year.
- Wage for clerical: $19.41 per hour.

Documenting Safety Risk Management				
Year	Airports	Hours/airport to document SRM	Total hours	Total Cost
1	268	0.00	0.00	$0
2	268	0.00	0.00	$0
3	268	26.00	6,968.00	$135,249
4	268	26.00	6,968.00	$135,249
5	268	26.00	6,968.00	$135,249
6	268	26.00	6,968.00	$135,249
7	268	26.00	6,968.00	$135,249
8	268	26.00	6,968.00	$135,249
9	268	26.00	6,968.00	$135,249
10	268	26.00	6,968.00	$135,249
Total			55,744.00	$1,081,991
Average per year			5,574.40	$108,199

viii. Reporting Safety Information Under Safety Assurance (§ 139.402(c)(3))

- Number of airports: 268.
- Estimated time needed to report safety information per report per airport: 1 hour per year starting in third year.
- Estimated number of reports per airport: 2 per year starting in third year.
- Wage for operational research analyst: $46.62 per hour.

Reporting Safety Information under Safety Assurance				
Year	Airports	Hours/airport to report safety information	Total hours	Total Cost
1	268	0.00	0.00	$0
2	268	0.00	0.00	$0
3	268	2.00	536.00	$24,988
4	268	2.00	536.00	$24,988
5	268	2.00	536.00	$24,988
6	268	2.00	536.00	$24,988
7	268	2.00	536.00	$24,988
8	268	2.00	536.00	$24,988
9	268	2.00	536.00	$24,988
10	268	2.00	536.00	$24,988
Total			4,288.00	$199,907
Average per year			428.80	$19,991

d. Annual Burden—FAA

i. Review of SMS Manual Revisions

- Number of airports: 268.
- Estimated time needed to review an SMS manual revision per airport: 1.25 hours per year starting in third year.
- Wage for inspector: $66.76 per hour.

Review of SMS Manual Revisions				
Year	Airports	Hours for manual revisions	Total hours	Total Cost
1	268			
2	268			
3	268	1.25	335.00	$22,365
4	268	1.25	335.00	$22,365
5	268	1.25	335.00	$22,365
6	268	1.25	335.00	$22,365
7	268	1.25	335.00	$22,365
8	268	1.25	335.00	$22,365
9	268	1.25	335.00	$22,365
10	268	1.25	335.00	$22,365
Total			2,680.00	$178,917
Average per year			268.00	$17,892

e. Summary of All Burden Hours and Costs—Certificate Holders

		Total Burden hours	Total Cost
1	Manual & Implementation Plan	232,248.00	$15,393,397
2	Manual Revisions	25,728.00	$499,380
3	Promotional Material	34,126.74	$2,261,920
4	Record Potential Hazards	27,872.00	$540,996
5	Hazard Awareness and Reporting Orientation Materials	4,288.00	$284,209
6	Update Distribution Log	9,166.67	$177,925
7	Update Training Records	737.50	$14,315
8	Documenting Safety Risk Management	55,744.00	$1,081,991
9	Reporting Safety Information under Safety Assurance	4,288.00	$199,907
	Grand Totals	394,198.90	$20,454,040
	Average per year	39,419.89	$2,045,404

Note: The sum of individual items may not equal totals due to rounding.

f. Summary of All Burden Hours and Costs—FAA

		Total Burden hours	Total Cost
1	Review of Manual & implementation Plan	4,872.00	$325,255
2	Review of SMS Manual Revisions	2,680.00	$178,917
	Grand Totals	7,552.00	$504,172
	Average per year	755.20	$50,417

Note: The sum of individual items may not equal totals due to rounding.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and believes its proposal corresponds with the intent of ICAO Annexes 14 and 19 standards.

G. Environmental Analysis

FAA Order 1050.1E defines the FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act (NEPA) in the absence of extraordinary circumstances. The FAA has determined this proposed rulemaking action qualifies for the categorical exclusion identified in Chapter 3, paragraph 312d and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed the proposal under the principles and criteria of Executive Order 13132, Federalism. Most airports subject to this proposal are owned, operated, or regulated by a local government body (such as a city or council government), which, in turn, is incorporated by or as part of a state. Some airports are operated directly by a state. The FAA does not believe this proposed rule has a significant adverse effect on Federalism. The FAA will mail a copy of the SNPRM to each state government specifically inviting comment on Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this SNPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a "significant energy action" under the executive order, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VII. How To Obtain Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, please send only one copy of written comments, or if you are filing comments electronically, please submit your comments only one time.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Proprietary or Confidential Business Information

Do not file in the docket information that you consider to be proprietary or confidential business information. Send or deliver this information directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document. You must mark the information that you consider proprietary or confidential. If you send the information on a disk or CD–ROM, mark the outside of the disk or CD–ROM and also identify electronically within the disk or CD–ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), when we are aware of proprietary information filed with a comment, we do not place it in the docket. We hold it in a separate file to which the public does not have access, and we place a note in the docket that we have received it. If we receive a request to examine or copy this information, we treat it as any other request under the Freedom of Information Act (5 U.S.C. 552). We process such a request under the DOT procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal (*http://www.regulations.gov*);
2. Visit the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/* or
3. Access the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680.

C. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 139

Air carriers, Airports, Aviation safety, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter I of Title 14, Code of Federal Regulations as follows:

PART 139—CERTIFICATION OF AIRPORTS

■ 1. The authority citation for part 139 is revised to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44709, 44719.

■ 2. Amend § 139.5 by adding in alphabetical order the definitions of the terms "Accountable executive", "Airport Safety Management System (SMS)", "Hazard", "Non-movement area", "Risk", "Risk analysis", "Risk mitigation", "Safety assurance", "Safety policy", "Safety promotion", and

"Safety risk management" to read as follows:

§ 139.5 Definitions.

* * * * *

Accountable executive means an individual designated by the certificate holder to act on its behalf for the implementation and maintenance of the Airport Safety Management System. The Accountable Executive has control of the certificate holder's human and financial resources for operations conducted under the Airport's Operating Certificate. The Accountable Executive has ultimate responsibility to the FAA, on behalf of the certificate holder, for the safety performance of operations conducted under the certificate holder's Airport Operating Certificate.

* * * * *

Airport Safety Management System (SMS) means an integrated collection of processes and procedures that ensures a formalized and proactive approach to system safety through risk management.

* * * * *

Hazard means a condition that could foreseeably cause or contribute to an aircraft accident as defined in 49 CFR 830.2.

* * * * *

Non-movement area means the area, other than that described as the movement area, used for the loading, unloading, parking, and movement of aircraft on the airside of the airport (including ramps, apron areas, and on-airport fuel farms).

* * * * *

Risk means the composite of predicted severity and likelihood of the potential effect of a hazard.

Risk analysis means the process whereby a hazard is characterized for its likelihood and the severity of its effect or harm. Risk analysis can be either a quantitative or qualitative analysis; however, the inability to quantify or the lack of historical data on a particular hazard does not preclude the need for analysis.

Risk mitigation means any action taken to reduce the risk of a hazard's effect.

* * * * *

Safety assurance means the process management functions that evaluate the continued effectiveness of implemented risk mitigation strategies; support the identification of new hazards; and function to systematically provide confidence that an organization meets or exceeds its safety objectives through continuous improvement.

Safety policy means the statement and documentation adopted by a certificate holder defining its commitment to safety and overall safety vision.

Safety promotion means the combination of safety culture, training, and communication activities that support the implementation and operation of an SMS.

Safety risk management means a formal process within an SMS composed of describing the system, identifying the hazards, and analyzing, assessing, and mitigating the risk.

* * * * *

§ 139.101 [Amended]

■ 3. Amend § 139.101 by removing paragraph (c).

■ 4. Amend § 139.103 by revising paragraph (b) to read as follows:

§ 139.103 Application for certificate.

* * * * *

(b) Submit with the application, two copies of an Airport Certification Manual, Safety Management System Implementation Plan (as required by § 139.403(b)), and Safety Management System Manual (where applicable) prepared in accordance with subparts C and E of this part.

■ 5. Amend § 139.203 by redesignating paragraph (b)(29) as (b)(30) and adding a new paragraph (b)(29) to read as follows:

§ 139.203 Contents of Airport Certification Manual.

* * * * *

(b)* * *

REQUIRED AIRPORT CERTIFICATION MANUAL ELEMENTS

Manual elements	Airport certificate class			
	Class I	Class II	Class III	Class IV
* * * *	*		*	*
29. Policies and procedures for the development of, implementation of, maintenance of, and adherence to the Airport's Safety Management System, as required under subpart E of this part. Section 139.401(a) prescribes which certificate holders are subject to this requirement.	X	X	X	X
* * * *	*		*	*

■ 6. Amend § 139.301 by revising paragraph (b)(1) and adding paragraphs (b)(9) and (b)(10) to read as follows:

§ 139.301 Records.

* * * * *

(b) * * *

(1) *Personnel training.* Twenty-four consecutive calendar months for personnel training records and orientation materials, as required under §§ 139.303, 139.327, and 139.402(d).

* * * * *

(9) *Safety risk management documentation.* Thirty-six consecutive calendar months or twelve consecutive calendar months, as required under § 139.402(b).

(10) *Safety communications.* Twelve consecutive calendar months for safety communications, as required under § 139.402(d).

* * * * *

■ 7. Amend § 139.303 by revising paragraphs (e)(5) and (e)(6) and by adding paragraph (e)(7) to read as follows:

§ 139.303 Personnel.

* * * * *

(e) * * *

(5) § 139.337, Wildlife hazard management;

(6) § 139.339, Airport condition reporting; and

(7) § 139.402, Components of airport safety management system.

* * * * *

■ 8. Add subpart E to part 139 to read as follows:

Subpart E—Airport Safety Management System

Sec.
139.401 General requirements.
139.402 Components of Airport Safety Management System.
139.403 Airport Safety Management System implementation.

Subpart E—Airport Safety Management System

§ 139.401 General requirements.

(a) Each certificate holder or applicant for an Airport Operating Certificate meeting at least one of the following criteria must develop, implement, maintain and adhere to an Airport Safety Management System:

(1) Is classified as a Large, Medium, or Small hub in the National Plan of Integrated Airport Systems;

(2) Is classified as a port of entry (under 19 CFR 101.3), designated international airport (under 19 CFR 122.13), landing rights airport (under 19 CFR 122.14), or user fee airport (under 19 CFR 122.15); or

(3) Has more than 100,000 total annual operations.

(b) The scope of an Airport Safety Management System must encompass aircraft operation in the movement area, aircraft operation in the non-movement area, and other airport operations addressed in this part.

(c) The Airport Safety Management System may correspond in size, nature, and complexity to the operations, activities, hazards, and risks associated with the certificate holder's operations.

(d) Each certificate holder required to develop, implement, maintain, and adhere to an Airport Safety Management System under this subpart must describe its compliance with the requirements identified in § 139.402 either:

(1) Within a separate section of the certificate holder's Airport Certification Manual titled Airport Safety Management System; or

(2) Within a separate Airport Safety Management System Manual. If the certificate holder chooses to use a separate Airport Safety Management System Manual, the Airport Certification Manual must incorporate by reference the Airport Safety Management System Manual.

(e) On an annual basis, the certificate holder shall provide the FAA copies of any changes to the Airport Safety Management Manual.

§ 139.402 Components of Airport Safety Management System.

An Airport Safety Management System must include:

(a) *Safety Policy.* A Safety Policy that, at a minimum:

(1) Identifies the accountable executive.

(2) Establishes and maintains a safety policy statement signed by the accountable executive.

(3) Ensures the safety policy statement is available to all employees and tenants.

(4) Identifies and communicates the safety organizational structure.

(5) Describes management responsibility and accountability for safety issues.

(6) Establishes and maintains safety objectives.

(7) Defines methods, processes, and organizational structure necessary to meet safety objectives.

(b) *Safety Risk Management.* Safety Risk Management processes and procedures for identifying hazards and their associated risks within airport operations and for changes to those operations covered by this part that, at a minimum:

(1) Establish a system for identifying operational safety issues.

(2) Establish a systematic process to analyze hazards and their associated risks by:

(i) Describing the system;

(ii) Identifying hazards;

(iii) Analyzing the risk of identified hazards and/or proposed mitigations;

(iv) Assessing the level of risk associated with identified hazards; and

(v) Mitigating the risks of identified hazards, when appropriate.

(3) Establish and maintain records that document the certificate holder's Safety Risk Management processes.

(i) The records shall provide a means for airport management's acceptance of assessed risks and mitigations.

(ii) Records associated with the certificate holder's Safety Risk Management processes must be retained for the longer of:

(A) Thirty-six consecutive calendar months after the risk analysis of identified hazards under paragraph (b)(2)(iv) of this section has been completed; or

(B) Twelve consecutive calendar months after mitigations required under paragraph (b)(2)(v) of this section have been implemented.

(c) *Safety Assurance.* Safety Assurance processes and procedures to ensure mitigations developed through the certificate holder's Safety Risk Management processes and procedures are adequate, and the Airport's Safety Management System is functioning effectively. Those processes and procedures must, at a minimum:

(1) Provide a means for monitoring safety performance including a means for ensuring that safety objectives identified under paragraph (a)(6) of this section are being met.

(2) Establish and maintain a hazard reporting system that provides a means for reporter confidentiality.

(3) Report pertinent safety information and data on a regular basis to the accountable executive. Reportable data includes:

(i) Compliance with the requirements under subpart D of this part;

(ii) Performance of safety objectives established under paragraph (a)(6) of this section;

(iii) Safety critical information distributed in accordance with paragraph (d)(5)(ii) of this section;

(iv) Status of ongoing mitigations required under the Airport's Safety Risk Management processes as described under paragraph (b)(2)(v) of this section; and

(v) Status of a certificate holder's schedule for implementing the Airport Safety Management System as described under paragraph (b)(2) of this section.

(d) *Safety Promotion.* Safety Promotion processes and procedures to foster an airport operating environment that encourages safety. Those processes and procedures must, at a minimum:

(1) Provide all persons authorized to access the airport areas regulated under this part with a hazard awareness orientation, which includes hazard identification and hazard reporting. These orientation materials must be readily available and be updated at least every 24 calendar months.

(2) Maintain a record of all hazard awareness orientation materials made available under paragraph (d)(1) of this section including any revisions and means of distribution. Such records must be retained for 24 consecutive months after the materials are made available.

(3) Provide safety training on those requirements of SMS and its implementation to each employee with responsibilities under the certificate holder's SMS that is appropriate to the individual's role. This training must be completed at least every 24 months.

(4) Maintain a record of all training by each individual under paragraph (d)(3) of this section that includes, at a minimum, a description and date of training received. Such records must be retained for 24 consecutive calendar months after completion of training.

(5) Develop and maintain formal means for communicating important safety information that, at a minimum:

(i) Ensures all persons authorized to access the airport areas regulated under this part are aware of the SMS and their safety roles and responsibilities;

(ii) Conveys critical safety information;

(iii) Provides feedback to individuals using the airport's hazard reporting system required under paragraph (c)(2) of this section; and

(iv) Disseminates safety lessons learned to relevant airport employees or other stakeholders.

(6) Maintain records of communications required under this section for 12 consecutive calendar months.

§ 139.403 Airport Safety Management System implementation.

(a) Each certificate holder required to develop, implement, maintain, and adhere to an Airport Safety Management System under this subpart must submit an implementation plan to the FAA for approval on or before [DATE 12 MONTHS AFTER EFFECTIVE DATE OF THE FINAL RULE].

(b) An implementation plan must provide:

(1) A detailed proposal on how the certificate holder will meet the requirements prescribed in this subpart.

(2) A schedule for implementing SMS components and elements prescribed in § 139.402. The schedule must include timelines for the following requirements:

(i) Developing the safety policy statement as prescribed in § 139.402(a)(2) and when it will be made available to all employees and tenants as prescribed in § 139.402(a)(3);

(ii) Identifying and communicating the safety organizational structure as prescribed in § 139.402(a)(4);

(iii) Establishing a system for identifying operational safety issues as prescribed in § 139.402(b)(1);

(iv) Establishing a hazard reporting system as prescribed in § 139.402(c)(2);

(v) Developing, providing, and maintaining hazard awareness orientation materials as prescribed in § 139.402(d)(1);

(vi) Providing SMS specific training to employees with responsibilities under the certificate holder's SMS as prescribed in § 139.402(d)(3); and

(vii) Developing, implementing, and maintaining formal means for communicating important safety information as prescribed in § 139.402(d)(5).

(3) A description of any existing programs, policies, or procedures that the certificate holder intends to use to meet the requirements of this subpart.

(c) Each certificate holder required to develop, implement, maintain, and adhere to an Airport Safety Management System under this subpart must submit its amended Airport Certification Manual and Airport Safety Management System Manual, if applicable, to the FAA in accordance with its implementation plan but not later than [DATE 24 MONTHS AFTER EFFECTIVE DATE OF THE FINAL RULE].

Issued in Washington, DC, under the authority provided by 49 U.S.C. 106(f) and 44706, on July 8, 2016.

Michael J. O'Donnell,

Director, Office of Airport Safety and Standards.

[FR Doc. 2016–16596 Filed 7–12–16; 11:15 am]

BILLING CODE 4910–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday
No. 135 July 14, 2016

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1
Amendments to Registration of Food Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2002–N–0323]

RIN 0910–AG69

Amendments to Registration of Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations for registration of food facilities that require domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA. This rule amends and updates FDA's registration regulations and is part of our implementation of the FDA Food Safety Modernization Act (FSMA), which added new provisions for the registration of food facilities. These amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

DATES: This rule is effective September 12, 2016.

FOR FURTHER INFORMATION CONTACT: Courtney Buchanan, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2487.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
Purpose and Coverage of the Final Rule
Summary of the Major Provisions of the Final Rule
Costs and Benefits
I. Background
  A. FDA Food Safety Modernization Act
  B. Purpose of This Rulemaking
  C. Summary of the Major Provisions of the Proposed Rule
  D. Public Comments
II. Legal Authority
III. General Comments on the Proposed Rule
IV. Comments on Proposed Amendments to § 1.227—Definitions
  A. Retail Food Establishment
  B. U.S. Agent
V. Comments on Proposed Amendments to § 1.230—When Must You Register or Renew Your Registration?
  A. Proposed § 1.230(a)—When Must You Register?
  B. Proposed § 1.230(b)—Registration Renewal
  C. Proposed § 1.230(c)—Abbreviated Registration Renewal Process
VI. Comments on Proposed Amendments to § 1.231—How and Where Do You Register or Renew Your Registration?
  A. Proposed § 1.231(a)—Electronic Registration and Registration Renewal
  B. Proposed § 1.231(b)—Registration or Registration Renewal by Mail or Fax
  C. Proposed §§ 1.231(a)(3) and (b)(5) and 1.234(c)(2) and (d)(5)—Unique Facility Identifier and Verification Procedures for FDA
  D. Proposed §§ 1.231(a)(4) and (b)(6), 1.234(c)(3) and (d)(6), and 1.235(c)(3) and (d)(6)—Verification Procedures for Submissions Not Made by the Owner, Operator, or Agent in Charge of the Facility
  E. Proposed §§ 1.231(a)(5) and (b)(7) and 1.234(c)(2) and (d)(5)—Verification Procedures for U.S. Agents
  F. Proposed § 1.231(a)(6) and (b)(9)—Requirement To Update Incorrect Registration Information
VII. Comments on Proposed Amendments to § 1.232—What Information Is Required in the Registration?
  A. Requirement for Certain Email Address Information
  B. Requirement for a Unique Facility Identifier
  C. Requirement To Include Food Product Categories
  D. Requirement To Identify Activity Type
  E. Requirement To Provide Assurance That FDA Will Be Permitted To Inspect
VIII. Comments on Proposed Amendments to § 1.233—Are There Optional Items Included in the Registration Form?
IX. Comments on Proposed Amendments to § 1.234—How and When Do You Update Your Facility's Registration Information?
X. Comments on Proposed Amendments to § 1.235—How and When Do You Cancel Your Facility's Registration Information?
XI. Comments on Proposed Amendments to § 1.241—What Are the Consequences of Failing To Register, Update, Renew, or Cancel Your Registration?
XII. Comments on Proposed Addition of § 1.245—Waiver Request
XIII. U.S. Agent Voluntary Identification System
XIV. Editorial Changes and Other Changes
  A. Editorial Changes
  B. CD–ROM Submissions
XV. Economic Analysis of Impacts
XVI. Paperwork Reduction Act of 1995
XVII. Analysis of Environmental Impact
XVIII. Federalism
XIX. References

Executive Summary

Purpose and Coverage of the Final Rule

This rule is part of FDA's implementation of FSMA (Pub. L. 111–353), which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule implements certain provisions in section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d), as amended by section 102 of FSMA, that relate to registration of food facilities. Furthermore, this rule amends and updates FDA's registration regulations and improves the utility of the food facility registration database to further enhance FDA's capabilities with respect to responding to food-related emergencies, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

Summary of Major Provisions of the Final Rule

Section 102 of FSMA amends section 415 of the FD&C Act by requiring that certain additional information be included in facility registrations. More specifically, section 102(a)(1)(A) of FSMA amends section 415 to provide that registrations for domestic food facilities are required to contain the email address for the contact person of the facility, and registrations for foreign food facilities are required to contain the email address of the U.S. agent for the facility. Further, section 102(a)(3) of FSMA amends section 415 to provide that food facilities required to register with FDA must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year, by submitting registration renewals to FDA. Also, section 102(b)(1)(A) of FSMA provides that all food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. These FSMA amendments were self-implementing and became effective upon enactment of FSMA. These FSMA amendments are included in this final rule to codify these provisions in 21 CFR part 1, subpart H, the food facility registration regulation.

In addition, section 102(b) of FSMA authorizes FDA to require that all food facility registrations be submitted to FDA in an electronic format; however, such requirement cannot take effect before the date that is 5 years after the date of enactment of FSMA (*i.e.*, January 4, 2016). We are implementing this provision in the final rule. However, we are delaying the date for mandatory electronic registration until January 4, 2020. Furthermore, we are including a waiver request provision in the rule to allow a registrant to submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, update, or cancellation to FDA electronically or to explain why it is not reasonable to provide the email address of the owner, operator, or agent in charge of the facility.

Section 102(c) of FSMA also directs FDA to amend the definition of the term "retail food establishment" in § 1.227 of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include: (1) The sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary. We are revising the definition of retail food establishment at § 1.227 in this final rule consistent with section 102(c) of FSMA.

In addition, we are making changes to improve the utility of the food facility registration database. We are making changes in 21 CFR part 1, subpart H to: (1) Require certain additional data elements in food facility registrations (*e.g.*, a unique facility identifier (UFI) for food facility registrations); (2) employ measures to verify certain information submitted in registrations; and (3) take additional steps to ensure that our registration database is up-to-date by identifying additional circumstances under which FDA will cancel registrations.

Further, we proposed to amend the regulation to shorten the timeframe for submitting updates and cancellations from 60 calendar days to 30 calendar days. In response to numerous comments received on this issue, the final rule does not shorten the timeframes as proposed. The final rule provides that updates to registration information or cancellation of registration must be submitted within 60 days of any change to any of the required information or the reason for the cancellation.

Costs and Benefits

Costs of meeting the requirements of this final rule will be incurred by both FDA and food facilities that are required to register.

Table 1 presents estimated costs associated with the provisions in this final rule. These costs are similar to what we estimated the proposed rule would cost, but with the additional implementation of a U.S. Agent Voluntary Identification System (VIS) and reduced costs to facilities resulting from postponing the requirements to provide a UFI and to submit registrations electronically. Estimated one-time costs to domestic and foreign facilities are about $27 million. These estimated costs include a small reduction from the estimated one-time costs of provisions in the proposed rule. As explained in the preliminary regulatory impact analysis (PRIA), one-time costs in the first year stem from the self-implementing FSMA provisions that are already effective, including learning costs (*i.e.*, the administrative costs incurred by domestic and foreign facilities in order to learn how to comply with any new regulation), first-time biennial registration renewal costs from the 2012 registration renewal cycle, and costs that stem from requirements for certain data elements in the registration form such as the email address for a domestic facility's contact person and the email address for a foreign facility's U.S. agent. These costs are approximately $20 million. Estimated one-time costs to domestic and foreign facilities for the biennial renewal cycle in 2016, by which time the final rule will be effective, include $4.6 million in one-time costs for entering additional data elements in the registration form and costs for U.S. agent verification procedures incurred in 2016. One-time costs in 2020 include the costs for the requirement to obtain a UFI plus the reduced costs associated with the mandatory electronic submission requirement (because the preamble to the final rule clarifies that food facilities will not be required to resubmit waivers with each biennial registration renewal cycle once FDA has granted the waiver). These costs are approximately $3 million.

Recurring biennial costs beginning in 2016 include costs from the requirement for both domestic and foreign food facilities to renew their registrations every 2 years and from requiring additional data elements in the registration form. Recurring costs for 2018 include costs from implementing the U.S. agent VIS. As was the case under Option 4 in the PRIA, these costs are based on the supposition that the U.S. agents for all foreign facilities will choose to use the VIS. In the PRIA (see pages 51 to 53), we estimated that implementing the system by 2018 could reduce estimated costs for the U.S. agent information viewing and verification provisions in the proposed rule by one-half. We estimated that this would result in roughly $2 million of savings each year or about $4 million every 2 years. We no longer assess the costs of requiring updates within 30 calendar days because we are not finalizing our proposal to shorten the time period for updates. The final rule does not change the currently required time periods. Thus, estimated recurring costs of this final rule are now approximately $8.8 million every 2 years. The $8.8 million in costs continue to accrue in each subsequent biennial registration renewal cycle, and include costs associated with registration renewal activities and costs associated with other provisions of the final rule, such as certain verification procedures.

Annualized costs are calculated using a discount rate of 7 percent and 3 percent over 20 years. Total annualized costs to food facilities, which include annualized one-time costs and annualized recurring costs, are approximately $4.7 million and $4.9 million per year ($24 and $25 per facility) using a discount rate of 7 percent and 3 percent, respectively, over a period of 20 years. Annualized recurring costs to FDA are approximately $0.9 and $1.2 million, also using a discount rate of 7 percent and 3 percent, respectively.

TABLE 1—ANNUALIZED COST AND BENEFIT SUMMARY

[$Millions]

	Total one-time costs	Total annualized costs 7%	Total annualized costs 3%	Benefits
Domestic Facilities	$9	$1.4	$1.4	Not Quantified.
Foreign Facilities	18	3.3	3.5	
Subtotal Facilities	27	4.7	4.9	

TABLE 1—ANNUALIZED COST AND BENEFIT SUMMARY—Continued

[$Millions]

	Total one-time costs	Total annualized costs 7%	Total annualized costs 3%	Benefits
Costs to FDA	....	0.9	1.2	
Total	27	5.6	6.1	

This analysis estimates costs and benefits of the provisions in this final rule only, which are assumed to accrue in addition to the estimated annual costs already incurred due to the implementation of the provisions in the 2003 interim final rule issued jointly by the Secretary and the Department of Homeland Security (DHS) jointly to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188) (68 FR 58894, October 10, 2003).[1] Those estimated costs were calculated in an economic impact analysis that accompanied the interim final rule (68 FR 58894 at 58932) (hereinafter referred to as the "2003 economic impact analysis"). For the final rule, the economic impact analysis was modified slightly with respect to the costs associated with the U.S. agent requirement at the final rule stage, which published in the **Federal Register** on October 3, 2005 (70 FR 57505 at 57506).

We also expect that at least some foreign food facilities could increase prices as a result of the costs they would have to incur as a result of the rule. Any such potential price increases that could occur as a result of compliance costs would likely be very small relative to the total costs to manufacture, process, pack, and hold foods for sale in the United States. We expect that the benefits of the final rule would include aiding FDA's ability to deter and limit the effects of foodborne outbreaks and other food-related emergencies. Although we are unable to quantify these and other benefits, we discuss the expected benefits qualitatively. (For a more complete qualitative discussion of the benefits, see the PRIA) (Ref. 1). In addition, we update in this analysis the monetized impact associated with different foodborne outbreak scenarios from the PRIA in order to determine the amount of savings from illness reduction that would be required in order for the final rule to reduce costs that result from foodborne illness by approximately the same amount that the compliance costs of the final rule would impose on food facilities. We expect the final rule would have additional benefits that we are similarly unable to quantify, including providing for the more efficient use of FDA's inspectional resources.

I. Background

A. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in Table 2 and requested comments on all aspects of these proposed rules.

TABLE 2—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls regulation.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety regulation.	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls regulation.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) or Importers of Food for Humans and Animals.	2013 proposed FSVP regulation ...	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification regulation.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration regulation.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation regulation.	79 FR 7006, February 5, 2014.

---

[1] The authorities of Treasury under section 701(b) of the FD&C Act (21 U.S.C. 371(b)) to jointly prescribe regulations with the Department of Health and Human Services for the efficient enforcement of section 801 of the FD&C Act (21 U.S.C. 381) were transferred to DHS when DHS was created by an act of Congress in 2002.

We also issued a supplemental notice of proposed rulemaking for the rules listed in Table 3 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 3—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice; Supplemental Notice.	79 FR 58574, September 29, 2014.

We finalized two of the foundational rulemakings listed in Table 4 in September 2015 and three additional rules in November 2015. In April 2016, we finalized the sanitary transportation regulation. In May 2016, we finalized the intentional adulteration regulation.

TABLE 4—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food.	Final human preventive controls regulation.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	Final animal preventive controls regulation.	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	Final produce safety regulation	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs (FSVP) or Importers of Food for Humans and Animals.	Final FSVP regulation	80 FR 74226, November 27, 2015.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	Final third-party certification regulation.	80 FR 74570, November 27, 2015.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	Final intentional adulteration regulation.	81 FR 34165, May 27, 2016.
Sanitary Transportation of Human and Animal Food	Final sanitary transportation regulation.	81 FR 20092, April 6, 2016.

Section 102 of FSMA, entitled Registration of Food Facilities, amends section 415 of the FD&C Act regarding requirements for food facility registration along with other sections of the FD&C Act involving food facility registration. Further, a number of provisions in FSMA apply to only facilities that are required to register under section 415 of the FD&C Act, including hazard analysis and risk-based preventive controls and mandatory recall authority.

With the finalization of the seven foundational rulemakings, we are putting in place a modern, risk-based framework for food safety that is based on the most recent science, that focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

After FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 2 to 4). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

B. Purpose of This Rulemaking

We published the proposed rule regarding amendments to registration of food facilities in the **Federal Register** on April 9, 2015 (80 FR 19160). We received numerous comments submitted on the proposed rule.

This rule is part of FDA's implementation of FSMA, which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This regulation would implement certain provisions in section 415 of the FD&C Act, as amended by section 102 of FSMA, that relate to registration of food facilities. In addition, this regulation amends and updates FDA's registration regulations and improves the utility of the food facility registration database to further enhance FDA's capabilities with respect to responding to food-related emergencies, and in addition, provides FDA with information that we can use to focus and better utilize our limited inspection resources.

C. Summary of the Major Provisions of the Proposed Rule

Section 102 of FSMA, entitled Registration of Food Facilities, amends section 415 of the FD&C Act regarding requirements for food facility registration along with other sections of the FD&C Act involving food facility registration. Further, other sections of FSMA include amendments that apply to facilities that are required to register under section 415 of the FD&C Act.

1. Section 102 of FSMA: Registration of Food Facilities

Section 102 of FSMA includes a number of amendments to food facility registration requirements or sections of the FD&C Act involving food facility registration. First, section 102 of FSMA amends section 415 by requiring that certain additional information be included in registrations. More specifically, section 102(a)(1)(A) of FSMA amends section 415 to provide that registrations for domestic food facilities are required to contain the email address for the contact person of the facility, and registrations for foreign food facilities are required to contain the email address of the U.S. agent for the facility. Also, section 102(b)(1)(A) of FSMA provides that all food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. These FSMA amendments were self-implementing and became effective upon enactment of FSMA. These FSMA amendments were included in the proposed rule to codify the provisions in 21 CFR part 1, subpart H, the registration of food facilities regulation.

Second, section 102 of FSMA amends section 415 with respect to updating food product category information required in food facility registrations. Before FSMA was enacted, section 415(a)(2) of the FD&C Act, as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), provided in relevant part that, when determined necessary by FDA "through guidance," a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3) of food manufactured, processed, packed, or held at such facility. On July 17, 2003, FDA issued a guidance document stating that FDA had determined that the inclusion of food product categories in food facility registrations was necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency (see 68 FR 42415). Section 102(a)(1)(B) of FSMA amends section 415(a)(2) of the FD&C Act with respect to food product category information by authorizing FDA to determine other food product categories, including those not specifically identified in § 170.3. Specifically, section 415(a)(2) of the FD&C Act, as amended by section 102(a)(1)(B) of FSMA, provides in relevant part that, when determined necessary by FDA "through guidance," a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. In October 2012, FDA issued a guidance entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (Ref. 5). This guidance represents FDA's conclusion on the necessity of food product categories in food facility registrations and identifies other food product categories that are necessary and appropriate for food facility registration, as provided by section 415(a)(2) of the FD&C Act.

Third, section 102(a)(3) of FSMA amends section 415 to provide that food facilities required to register with FDA must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year, by submitting registration renewals to FDA. Further, section 102(a)(3) of FSMA directs FDA to provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the preceding registration or registration renewal for the facility.

Fourth, section 102(b) of FSMA amends section 415(b) of the FD&C Act by adding new provisions authorizing FDA to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that created, caused, or was otherwise responsible for such reasonable probability; or knew of, or had reason to know of, such reasonable probability and packed, received, or held such food. Under section 415(b)(4) of the FD&C Act, as amended by section 102(b) of FSMA, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States. Under section 301(d) of the FD&C Act (21 U.S.C. 331(d)), as amended by section 102(b) of FSMA, the introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act. Further, section 801(l) of the FD&C Act, as amended by section 102(b) of FSMA, provides, in relevant part, that an article of food being imported or offered for import into the United States that is from a foreign facility for which a registration has been suspended under section 415 must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article. FDA intends to address the suspension of registration provisions in section 102(b) of FSMA in a separate rulemaking.

Section 102(b) of FSMA also authorizes FDA to require that all food facility registrations be submitted to FDA in an electronic format; however, such requirement cannot take effect before the date that is 5 years after the date of enactment of FSMA (*i.e.,* January 4, 2016). We proposed to add a waiver request provision to allow a registrant to submit a written request to FDA that explains why it is not reasonable to submit the registration or registration renewal to FDA electronically.

Lastly, section 102(c) of FSMA directs FDA to amend the definition of the term "retail food establishment" in § 1.227 of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include: (1) The sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

2. Discussion of Other FSMA Amendments Involving Food Facilities Required To Register Under Section 415 of the FD&C Act

In addition to amending section 415 of the FD&C Act and the other related sections of the FD&C Act as discussed in the preceding section, FSMA also amended the FD&C Act such that section 415 functions in connection with other food safety provisions. For instance, FSMA added section 418 of the FD&C Act (21 U.S.C. 350g), which establishes certain preventive control requirements for food facilities that are required to register under section 415. In general, section 418(a) requires the owner, operator, or agent in charge of a "facility" to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. The term "facility" is defined in section 418(o)(2) as "a domestic facility or a foreign facility that is required to register under section 415."

In addition, section 201(a) of FSMA created section 421 of the FD&C Act (21 U.S.C. 350j), which also ties to section 415. In particular, section 421 requires the Agency to identify high-risk "facilities" and mandates more frequent inspections for domestic high-risk "facilities" than for domestic non-high-risk facilities. Section 421 also includes an inspection mandate for foreign facilities. For the purposes of section 421, the term "facility" refers to facilities that are required to register under section 415. (See section 421(e)). In addition, section 306 of FSMA added section 807(a)(1) of the FD&C Act (21 U.S.C. 384c(a)(1)), which provides that FDA may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415.

FSMA also created section 423 of the FD&C Act (21 U.S.C. 3501), which provides a "responsible party" an opportunity to voluntarily cease distribution and recall a food under specified circumstances and also provides FDA with authority to mandate a recall under specified circumstances. The term "responsible party" is defined by reference to the definition in section 417 of the FD&C Act (21 U.S.C. 350f), which in turn defines that term as a person that submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act, at which such article of food is manufactured, processed, packed, or held. (See section 417(a)(1) of the FD&C Act.) In addition, FSMA created section 808 of the FD&C Act (21 U.S.C. 384d), which provides for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits of foreign food entities, including foreign food facilities registered under section 415.

Further, section 107 of FSMA amended the FD&C Act to provide FDA with the authority to collect fees related to reinspections of facilities required to register under section 415 of the FD&C Act. Specifically, section 107 of FSMA added section 743(a)(1)(A) of the FD&C Act (21 U.S.C. 379j–31(a)(1)(A)), which provides FDA with the authority to assess and collect fees from domestic facilities (as defined in section 415(b) of the FD&C Act) and U.S. agents for foreign facilities (also as defined in section 415(b) of the FD&C Act) subject to reinspection to cover reinspection-related costs.

FSMA is not the only act in which Congress has linked food facility registration to specific food safety requirements. The Food and Drug Administration Amendments Act of 2007 (FDAAA) also tied food safety requirements to food facility registration. FDAAA amended the FD&C Act by creating section 417, which generally requires a "responsible party" to submit a report to FDA through the Reportable Food Registry after determining that an article of food is a reportable food as defined in section 417(a)(2) and further defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)). As stated previously, section 417 of the FD&C Act defines the term "responsible party" as a person that submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act, at which such article of food is manufactured, processed, packed, or held. (See section 417(a)(1) of the FD&C Act.)

As a result of these links between food facility registration and additional requirements in the FD&C Act, food facility registration now serves additional functions to those originally identified in the food facility registration regulations issued in 2003 and finalized in 2005 (68 FR 58894; 70 FR 57505). More specifically, the interim final rule noted that food facility registration would help FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies (68 FR 58894 at 58895). It also noted that registration would provide FDA with information about food facilities that would help FDA and other authorities determine the source and cause of an outbreak of foodborne illness, while also enabling FDA to notify more quickly the facilities that might be affected by the outbreak (68 FR 58894 at 58895). While food facility registration continues to serve all of those functions, with the passage of FSMA and FDAAA, food facility registration now also serves to determine the applicability of provisions in other sections of the FD&C Act, including sections 417, 418, 421, 423, 743, 807, and 808 of the FD&C Act. Thus, food facility registration now relates to many more food safety requirements than when the system was first implemented in 2003.

3. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

Section 103(c)(1)(A) of FSMA, regarding Hazard Analysis and Risk-Based Preventive Controls, requires that the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations with respect to "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership" within the context of section 415 of the FD&C Act. Section 103(c)(1)(B) of FSMA provides that such rulemaking will "enhance the implementation of . . . section 415 and clarify the activities that are included as part of the definition of the term 'facility' under such section 415." In the **Federal Register** of January 16, 2013 (78 FR 3646), we published a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" to implement section 103 of FSMA and we discuss our proposal to revise the registration of food facilities regulations (part 1, subpart H) as specified by section 103(c)(1) of FSMA. In the **Federal Register** of September 29, 2014 (79 FR 58524), we published a supplemental notice of proposed rulemaking to amend the 2013 preventive controls proposed rule. We finalized the rulemaking on September 17, 2015. See "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food," 80 FR 55908. That rule is a separate rulemaking and not the subject of this rulemaking.

D. Public Comments

We received over 1,000 submissions on the proposed amendments to food facility registration rule by the close of the comment period, each containing one or more comments on various aspects of the proposal. We received submissions from a wide array of members of the public, including individual farmers; cooperatives; coalitions; trade organizations;

consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; government agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments addressed numerous provisions of the proposed food facility registration rule, including our requests for comments on various topics. Some comments addressed issues that are outside of the scope of this rule. We do not discuss such comments in this document.

In sections III through XIII of this document, we describe the comments we received on the rule, respond to them, and explain any changes we made to the proposed food facility registration rule. We discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements.

II. Legal Authority

We are issuing this final rule under the FD&C Act, FSMA, and the Bioterrorism Act. FDA's legal authority to implement requirements of section 102 of FSMA derives from section 102 of FSMA and sections 415, 301(dd), 801(l), and 701(a) of the FD&C Act. As discussed previously, section 415 of the FD&C Act requires food facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA by submitting certain information to the Agency and updating such information as necessary. Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, requires, in relevant part, food facility registrations to include additional information, including the email addresses of contact persons for domestic facilities and U.S. agents for foreign facilities; an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act; and updated food product category information, if determined necessary and appropriate by FDA. Further, section 415(a)(3) of the FD&C Act, as amended by section 102 of FSMA, requires, in relevant part, food facilities required to register to renew their registrations with FDA between October 1 and December 31 of each even-numbered year, and directs FDA to provide for an abbreviated registration renewal process for registrants that have not had any changes to registration information since the registrant submitted the preceding registration or registration renewal for the facility involved. Section 301(dd) of the FD&C Act provides that failure to register in accordance with section 415 of the FD&C is a prohibited act. Section 801(l) of the FD&C Act provides that an article of food being imported or offered for import into the United States that is from a foreign facility for which a registration has not been submitted to FDA under section 415 (or for which a registration has been suspended under such section) must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article until the foreign facility is so registered. Section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. As discussed previously, section 102(c) of FSMA also directs FDA to amend the definition of the term "retail food establishment" in FDA's Registration of Food Facilities Regulation at § 1.227.

As discussed in this final rule, we are revising our regulations to require additional data elements in food facility registrations to provide for more efficient and effective communications during a public health emergency and to provide FDA information that we can use to focus and better deploy the Agency's limited inspectional resources. FDA's legal authority to implement these and other changes to improve the utility of the food facility registration database also derives from section 102 of FSMA and the sections of the FD&C Act described in the previous paragraph. Section 415(a)(2) of the FD&C Act requires foreign facilities to submit registrations to FDA that include the name of the U.S. agent for the facility. Further, FDA is relying on section 107 of FSMA and sections 421 and 704 (21 U.S.C. 374) of the FD&C Act in issuing these proposed changes. Section 107 of FSMA amended the FD&C Act to provide FDA with the authority to assess and collect certain fees from, *inter alia,* U.S. agents for foreign facilities (as defined in section 415(b) of the FD&C Act) subject to reinspection to cover reinspection-related costs. Section 704 gives FDA the authority to inspect factories, warehouses, and other establishments in which foods are manufactured, processed, packed, or held. Section 421 of the FD&C Act requires the Agency to identify high-risk facilities and mandates more frequent inspections for domestic high-risk facilities than for domestic non-high-risk facilities. FDA is also relying on section 305(d) of the Bioterrorism Act, which directs FDA, in relevant part, to ensure adequate authentication protocols are used to enable identification of the registrant and validation of the registration data, as appropriate, for registrations submitted to FDA electronically. Thus, FDA has the authority to issue this rule under section 305 of the Bioterrorism Act, sections 102 and 107 of FSMA, and sections 301(dd), 415, 701(a), 704, and 801 of the FD&C Act.

We are including in this final rule the requirements of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA, as discussed previously, in the Registration of Food Facilities regulation (21 CFR part 1, subpart H). In addition, we are including in this final rule other requirements of section 102 of FSMA, such as mandatory electronic registration submissions and amendments to the definition of "retail food establishment" in § 1.227. Lastly, we are including in this final rule other changes to improve the utility of the food facility registration database and adding a waiver request provision to allow a facility to submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, updates, and cancellations to FDA electronically or to explain why it is not reasonable to provide the email address of the owner, operator, or agent in charge of the facility.

III. General Comments on the Proposed Rule

(Comment 1) Comments urge FDA to exempt all facilities that make less than $500,000 a year in sales who also sell most of their food locally.

(Response 1) To the extent that the comment is asking that all facilities with annual sales of less than $500,000 be exempt from the registration requirement, we do not agree. Neither the Bioterrorism Act nor the FSMA amendments regarding food facility registration exempt facilities from the requirement to register based on their size. Furthermore, facilities under this size may be linked to food-related emergencies, and having registration information for these facilities can facilitate FDA's response to such emergencies.

(Comment 2) Several comments state that small food producers or hobbyists who make food out of their home and also sell the food at farmers' markets and to other consumers should not be required to register.

(Response 2) Under 21 CFR 1.227, a private residence is not a "facility" and thus, is not required to be registered. A private residence must meet customary expectations for a private home and does not otherwise include commercial facilities in which a person also happens to reside. Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered. Accordingly, if the activities of small food producers or hobbyists meet customary expectations for a private residence, the producers or hobbyists would not be required to register.

(Comment 3) One comment requests that FDA exclude seed conditioning facilities that direct some seeds to animal food use from the requirement to register. The comment describes seed conditioning facilities as facilities that clean, grade, size, disinfect, dry, sort, screen, fumigate, and/or blend seeds to prepare seed intended for cultivation for commercial sales. The comment states that these establishments do not intend to manufacture, process, pack, or hold food for consumption and are therefore "not in the animal food business." The comment states that such establishments instead intend to prepare seed for planting purposes. The comment states that when some seeds become cracked, damaged during the process, or they may not be suitable for cultivation, they cannot be used for planting. In those situations, the establishment may direct the seeds for use in animal food (or, alternatively, may direct the seeds for incineration and landfilling). The comment further states that establishments may direct the seeds for animal food use if there is an oversupply of seeds that would otherwise be cultivated. In addition, the comment asks that FDA revise the Agency's "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)" to state that seed conditioning facilities are not required to register. In that guidance, FDA stated that an establishment that manufactures/processes and sells seed to farmers is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. However, if the seed is reasonably expected only to be cultivated, the guidance states that the establishment is not required to be registered. The comment states that because FSMA added certain preventive control requirements under section 418 of the FD&C Act for food facilities that are required to register under section 415, FDA should rethink the aspect of the registration guidance regarding seed conditioning. The comment states that establishments that are required to register are now subject to more considerable regulatory requirements.

(Response 3) FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the United States. "Food" is defined in section 201(f) of the FD&C Act to include articles used for food or drink for man or other animals. The comment states that seed conditioning establishments should not be required to register because they do not intend to manufacture, process, pack, or hold food for animal consumption. We decline to provide any specific exclusions for seed conditioning establishments from the requirements for registration. As we stated in the Agency's "Guidance for Industry: Questions and Answers Regarding Food Facility Registration," an establishment that conditions seed for planting purposes is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to food use, including animal food use or as an ingredient in animal food (Ref. 6). Whether a particular establishment is required to register will depend on the specific nature of the establishment. The comment describes establishments that may direct cracked, damaged, culled, or excess seeds for use in animal food. If an establishment that manufactures/process, packs, or holds the seed reasonably believes that the seed is reasonably expected to be directed to such food use, the establishment must be registered. The comment also states that some establishments may direct such cracked, damaged, culled, or excess seeds for incineration and landfilling. If a seed conditioning establishment directs the seeds only to uses such as cultivation or to destruction (such as incineration or landfill), the establishment would not be required to register.

Discussion on the application of the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" rule (80 FR 56170, September 17, 2015) is outside the scope of this rule making.

(Comment 4) A comment suggests that FDA should reconsider whether foreign facilities should be required to register. The comment states that most countries have an authorization or registration system and businesses in those countries will already be registered with the relevant authority in their country. The comment states that where FDA has a relationship with a foreign authority, the foreign registration could be accepted as assurance that foreign businesses are in good standing with the national competent authority. The comment also states that the requirement to register is particularly onerous for foreign businesses and that many foreign businesses are not familiar with the norms of U.S. government agencies.

(Response 4) We disagree that a foreign facility should not be required to register. Section 415(a)(1) of the FD&C Act requires that each domestic and foreign facility be registered. "Facility" is defined as "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food" (21 U.S.C. 350d(c)(1)). In addition, "foreign facility" is defined as a facility that "manufactures, processes, packs, or holds food, but only if food from such a facility is exported to the United States for consumption in this country without further processing or packaging outside the United States" (21 U.S.C. 350d(c)(3)(A)). Therefore, food facilities that are foreign facilities and do not qualify for an exemption under § 1.226 must register. Further, obtaining registration information from other foreign government agencies would not guarantee that FDA has all of the required information for food facility registration purposes for all foreign facilities. Foreign governments might not require the same registration information as required in this final rule, in part because the registration systems in foreign countries might serve different purposes from FDA's. The registration information required in this final rule is designed to assist FDA in responding to bioterrorist or other food-related emergencies and to assist FDA in better utilizing its limited inspection resources, among other purposes.

(Comment 5) Several comments recommend amending the definition of retail food establishment to exclude vending machines that manufacture food within the vending unit itself before selling it directly to the consumer. Comments state that vending machines should have to register and that self-serve ice vending machines are packaging ice and reselling packaged food to retail clients. The comments state that an outbreak in foodborne illness linked to retail vending machines would have a devastating impact on the packaged ice industry as a whole.

(Response 5) Under § 1.227, a "retail food establishment" includes grocery stores, convenience stores, and vending machines. We disagree that we should amend the definition of retail food establishment to remove vending machines. Vending machines that sell food products directly to consumers as their primary function are properly exempt from registration as retail food establishments. This is consistent with section 415(c)(1) of the FD&C Act, which provides that the term "facility" does not include retail food establishments. We acknowledge that outbreaks in any segment of industry have a significant impact. We note, however, that while vending machines and other retail food establishments are not required to register, they still have responsibility for ensuring the safety of their products.

(Comment 6) One comment encourages FDA to require farms to register to prevent what the comment describes as a gap in oversight.

(Response 6) FDA declines to require farms to register as food facilities under section 415 of the FD&C Act. The requirement in section 415 that a facility must register does not apply to farms. See section 415(c) of the FD&C Act (providing that the term "facility" does not include farms). The comment does not explain how requiring farms to register would be consistent with section 415.

(Comment 7) One comment requests modifications to Form FDA 3537. In particular, the comment requests that the registration system should clear all information from section 13 of the current Form FDA 3537 whenever a registration is updated or renewed. The comment also states that many owners, operators, or agents in charge of a facility may be corporations, not individuals, and therefore suggests that FDA add a field linked to the requirement that facilities provide the email address for the owner, operator, or agent in charge. Specifically, the comment requests that facilities be able to provide the name of the individual associated with that email address. The comment also recommends making technical edits to the electronic version of the form, such as changes to the pull-down selections in the Facility Name Suffix category (allowing facilities to indicate, for instance, whether they are cooperatives or limited liability corporations) and the automatically populated telephone country codes.

(Response 7) Section 13 of the current Form FDA 3537 includes a certification statement providing that the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator or agent in charge of the facility, must submit the form. The certification states that by submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the registration information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to FDA also certifies that the registration information is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. Section 13 also provides for the individual authorized by the owner, operator, or agent in charge to identify the individual who authorized submission of the registration and to provide specified contact information for that individual. With regard to the electronic version of Form FDA 3537, section 13 of the form prepopulates with information (as do the other fields). This is done to keep the process for registration renewal or updates as streamlined as possible. We understand that some applicants will need to edit this section to indicate changes to who submits the form, while others may not. Therefore, we decline the recommendation to not pre-populate this section for electronic registration renewals or updates. In addition, we decline the recommendation to require the name of the individual associated with the email address provided for the owner, operator, or agent in charge. We currently believe that the final rule already requires sufficient facility contact information. However, we will consider adding an optional field for an individual's name associated with the required email address in a future version of Form FDA 3537. If we add such a field, we will issue a guidance document in accordance with our good guidance practice (GGP) regulations in 21 CFR 10.115 describing this change.

With regard to the requested additional technical changes to the electronic version of the form, we will consider the recommendations and make changes if appropriate.

(Comment 8) A comment suggests that FDA should share the list of registered businesses with the authorities in the relevant third country.

(Response 8) FDA's list of registered facilities and registration documents are not subject to disclosure under the Freedom of Information Act (FOIA). In addition, any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person also is not subject to disclosure under FOIA (21 U.S.C. 350d(a)(5)).

However, FDA believes that in certain circumstances it may be appropriate to share information derived from our registration database with foreign government officials consistent with FDA's laws and procedures. Any sharing of information with another foreign government would typically be done under 21 CFR 20.89, which includes confidentiality provisions.

IV. Comments on Proposed Amendments to § 1.227—Definitions

We proposed to replace the phrase "the owner, operator, or agent in charge of a facility" with "you" throughout the regulatory text in 21 CFR part 1, subpart H, because "you" is defined in current § 1.227 to mean the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States. We are finalizing this change as proposed.

Furthermore, we note that we have redesignated all definitions in § 1.227 in 21 CFR part 1, subpart H, to eliminate paragraph designations (such as (a) and (b)). FDA made this change in the final rule for "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food" (80 FR 55908).

A. Retail Food Establishment

Under section 415 of the FD&C Act and FDA's registration regulation (21 CFR 1.226(c)), a retail food establishment is not required to register with FDA. A "retail food establishment" is defined in current § 1.227 to mean an establishment that sells food products directly to consumers as its primary function.

A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The definition of retail food establishment also provides that the term "consumers" does not include businesses, and a "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. Section 102(c) of FSMA directs FDA to amend the definition of "retail food establishment" to clarify that, in determining the primary function of an establishment, the sale of food directly to consumers by such establishment includes: (1) The sale of food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary. In addition, section 102(c) provides that the term "consumer" does not include a business.

We proposed to amend § 1.227 to address off-farm sales by an establishment located on a farm. Specifically, we proposed to clarify that all sales by an on-farm establishment do not have to be on the farm by specifically addressing how off-farm sales directly to consumers are to be counted in determining whether the on-farm establishment is a retail food establishment. We proposed that, in determining the primary function of an establishment located on a farm, the sale of food directly to consumers from such an establishment would include sales at a roadside stand or farmer's market, and that the roadside stand or farmers' market would not need to be on the farm where the establishment is located. In determining the primary function of an establishment located on a farm, we also proposed that the sale of food directly to consumers would also include the sale and distribution of such food through a community supported agriculture program (CSA). In addition, we proposed that the sale of food directly to consumers would include the sale and distribution of such food at other direct-to-consumer platforms, including door-to-door sales; mail, catalog and Internet orders; online farmers' markets and online grocery deliveries; religious or other organization bazaars; and state and local fairs.

We proposed to define "roadside stand", "farmers' market", and "community supported agriculture program" in § 1.227, based on definitions found in 7 CFR 249.2. Specifically, we proposed to specify that a farmers' market would mean a location where one or more local farmers assemble to sell from their farms directly to consumers and that a roadside stand would mean a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers.

Finally, we proposed that a CSA program would mean a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. Under our proposal, this would include CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers.

We requested comment on what, if any, limitations should be included in the proposed definitions for roadside stands and farmers' markets, such as distance of the roadside stand or farmers' market from the farm (80 FR 19160 at 19166). In addition, we requested comment on whether it is appropriate to limit the amendment to the retail food establishment definition to on-farm establishments, as we proposed (Id.). We also requested comment on whether we should provide that off-farm sales to businesses also be considered in determining an establishment's primary function (Id.).

1. Applicability to On-Farm Establishments

(Comment 9) Numerous comments state that the amendment to the retail food establishment definition should not be limited to on-farm establishments. These comments maintain that it should not matter if an establishment is on a farm. Some comments state that there is no statutory language directing or justifying the proposal to limit the amendment of the retail food establishment definition to on-farm establishments. Comments suggest that Congress intended the law to apply equally to all direct-to-consumer sales from farms, whether the sales occur on, or off, the farm. One comment indicates that this definition should reflect the reality of modern farming operations. One comment also states that local and regional food entrepreneurs make use of shared commercial kitchens and have no storefronts from which to make sales, and that the limitation of the amendment to on-farm establishments would mean that these entities would have to register even if all of their sales are directly to consumers.

(Response 9) We are convinced by the comments to expand the amendment to the retail food establishment definition to include some non-farm establishments. In particular, we agree with the comments that we should revise the retail food establishment definition to reflect modern farming-related practices. We agree that limiting the amendment to on-farm establishments is overly simplistic, given the diverse ways farmers today engage in value-added processing of their raw agricultural commodities (RACs).

The comments raise the question of what type of businesses section 102(c) of FSMA is intended to address. In construing the scope of section 102(c) of FSMA, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (*Chevron* step one)? (*Chevron U.S.A., Inc.*, v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984)). If the "intent of Congress is clear," an Agency "must give effect to the unambiguously expressed intent of Congress." Id. at 843. However, if "Congress has not directly addressed the precise question at issue," and the statute is "silent or ambiguous with respect to the specific issue," then our interpretation of the term "establishment" will be upheld as long as it is based on a "permissible construction of the statute" (*Chevron* step two). *Chevron*, 467 U.S. at 842–43; *FDA* v. *Brown & Williamson Tobacco Corp*, 529 U.S. 120, 132 (2000).) To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. See *e.g., Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986). We have determined that, in enacting section 102(c) of FSMA, Congress did not speak directly and precisely to the provision's scope. For instance, in section 102(c)(1) of FSMA, Congress provided that FDA amend the definition of retail food establishment to clarify that, "in determining the primary function of an *establishment* or a retail food establishment under such section," the sale of certain direct-to-consumer foods should be counted (emphasis added). An "establishment" could be any number of types of businesses. An "establishment" could be any business that manufactures/processes, packs, or holds food for consumption in the United States. Alternatively, an "establishment" could be the type of business that commonly sells foods at the direct-to-consumer platforms enumerated in section 102(c) of FSMA (*i.e.*, at roadside stands, farmers' markets, and CSAs).

The language in section 102(c) of FSMA provides an express delegation of authority to the Secretary to amend the definition of the term "retail food establishment" in § 1.227 to provide for the inclusion of certain specified sales (*i.e.*, farmers' market, roadside stand, and CSA sales) in determining an establishment's primary function (FSMA section 102(c)(1)(A)-(B)), as well as other sales that the Agency may determine (FSMA section 102(c)(1)(C)). The decision to direct the Secretary to amend § 1.227, and the decision to provide that certain sales may be included as determined by the Secretary, contemplates the Secretary having certain discretion in effectuating the amendment. While Congress intended for certain specific sales (*i.e.*, farmers' market, roadside stand, and CSA sales) to be counted in conducting a primary function analysis, Congress did not specify to what kind of businesses the new analysis would apply. Instead, Congress left a gap for the Secretary to fill by regulation.

Because Congress left a gap for the Secretary to fill, under *Chevron* step two FDA may interpret the scope of FSMA section 102(c)(1), provided that FDA's interpretation is not arbitrary, capricious, or manifestly contrary to the statute. *Chevron,* 467 U.S. at 843 (noting that if a statute is silent with respect to an issue the Agency's answer to the issue should be based on a permissible interpretation of the statute).

The language in section 102(c) of FSMA does not specifically prescribe the provision's scope, but it does provide examples of the kind of circumstances in which Congress intended the retail food establishment amendment applying. In directing the Secretary to include certain sales in determining the primary function, section 102(c) directs the Secretary to include sales at roadside stands and farmers' markets located other than where the food was manufactured or processed, as well as CSAs (FSMA section 102(c)(1)(A)–(B)). Sales platforms such as these are closely associated with food produced by farmers. Even in section 102(c)(1)(C) of FSMA, Congress directed the Secretary to include the sale and distribution of "*such* food at any other *such* direct sales platform" as determined by the Secretary (emphasis added). This suggests that the other platforms Congress contemplated were platforms that were akin to those listed in section 102(c)(1)(A)–(B) and involved food akin to that contemplated by section 102(c)(1)(A)–(B). Given that farmers represent the overwhelming majority of businesses that commonly sell foods at the direct-to-consumer platforms enumerated in section 102(c) of FSMA (*i.e.,* at roadside stands, farmers' markets, and CSAs), it is reasonable to interpret section 102(c) of FSMA as applying to farmers and businesses closely tied to farms. Under this interpretation, section 102(c) allows farmers to manufacture/process food for sale without triggering registration, provided that the primary function of the farmer's manufacturing/processing operation is the sale of food directly to consumers.

Our proposal to clarify the retail food establishment definition recognized that some farmers conduct manufacturing/processing. However, our proposed clarification would have only applied to establishments located on farms. We recognize that while some farmers have the space and equipment on their farms to manufacture/process foods for sale at direct-to-consumer platforms, other farmers conduct value-added processing off of the farm, such as by renting space at a shared kitchen. The clarification to the retail food establishment definition that we included in the proposed rule would have captured the on-farm operations, but not the off-farm operations.

Because farmers conduct manufacturing/processing in establishments located on farms and off of farms, we conclude that it is reasonable to interpret section 102(c) of FSMA to apply to on-farm establishments and certain off-farm operations tied to farms. Accordingly, we have finalized our proposal to address off-farm sales by establishments located on farms. In addition, in the final rule, we have revised the retail food establishment definition to also state that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers: At a roadside stand or farmers market; through a CSA; and at other such direct-to-consumer sales platforms. By "farm-operated business," we mean a business that is managed by one or more farms and that conducts manufacturing/processing not on the farm(s). Thus, under the final rule, an establishment located on a farm that sells apples it grows and apple pies it manufactures directly to consumers at a farmer's market would consider those sales in determining its primary function. At the same time, if a farmer manufactures or manages the manufacturing of jellies from the apples that he grows at an off-farm location, such as an incubator kitchen, and sells those jellies at a farmer's market, the jelly-making operation would be a farm-operated business and may consider those sales in determining its primary function.

We recognize that some farmers rent space at off-farm manufacturing/processing facilities, like shared kitchens, to conduct value-added processing. The "business" we are referring to in "farm-operated business" is the business entity conducting the manufacturing/processing operations. The ownership of the physical building, *e.g.,* the ownership of the shared kitchen, where the manufacturing/processing occurs is not relevant. Thus, if an apple grower leases space at an off-farm incubator kitchen to manufacture apple jellies, ownership of the incubator kitchen building would not be relevant. Because the apple farmer manages the off-farm apple jelly manufacturing operation, the apply jelly manufacturing operation is a farm-operated business and eligible for the retail food establishment exemption from registration.

In addition, we recognize that some farms are members of cooperatives that pool RACs grown, harvested, or raised by member farms for value-added processing. The phrase "one or more farms" in the explanation of the meaning of "farm-operated business" allows cooperatives comprised of multiple farms performing certain manufacturing/processing activities to be eligible for the retail food establishment exemption from registration.

Regarding the example of shared commercial kitchens in the comment, if an establishment is a retail food establishment under § 1.227, a commercial kitchen that is co-located with, and thus, part of, the retail food establishment, is not required to be registered.

2. Sale of Food Directly to Consumers at a Roadside Stand or Farmers' Market

(Comment 10) One comment states that farmers' markets and roadside stands should be considered retail food establishments, including those markets and stands that handle products or produce grown on a particular farmer's property.

(Response 10) We agree that farmers' markets and roadside stands may be considered retail food establishments even when they sell products not manufactured or grown on the property of the farmers selling those foods. The test for whether such farmers' markets and roadside stands are retail food establishments is whether they sell food directly to consumers as their primary function. The food sold directly to consumers can be produced by the farmers selling the food, but need not be.

(Comment 11) One comment states that because farms may aggregate food produced by other farms, the definition for farmers' markets should not specify that the food sold by local farmers is "from their farms." Comments also argue that the definition of roadside stands and farmers' markets should encompass stands at which any vendors sell food directly to consumers, and that it should not be limited to stands at which farmers sell food from their farms directly to consumers as FDA proposed.

(Response 11) The definitions of farmers' markets and roadside stands are based on definitions found in 7 CFR 249.2, and we are wary of adopting definitions of these terms that are significantly different from the definitions of the same terms held by

USDA. Moreover, we do not believe that changing the definitions as suggested by the comments would have any practical effect. That's because the presence of non-farmers at a farmers' market or roadside stand would not mean that a location that would otherwise meet the definition of a farmers' market or roadside stand would not be considered a farmers' market or roadside stand.

Further, whether food is sold at farmers' markets or roadside stands is less important for the purposes of this rule than whether the food is sold directly to consumers. An establishment is exempt from registration as a retail food establishment if the establishment's primary function is to sell food directly to consumers, regardless of whether the food is sold through farmers' markets, roadside stands, or other direct-to-consumer platforms. Farmers' markets and roadside stands are examples of direct-to-consumer sales platforms that are specifically mentioned in the amendment to the definition of retail food establishment, but the catchall provisions in paragraphs (1)(iii) and (2)(iii) provide that the sale of food directly to consumers includes the sale and distribution of food at other direct-to-consumer platforms. As a result, changing the definitions of farmers' market and roadside stand as the comments suggest would have little, if any, impact on the scope of this rule. Therefore, we decline the comments' suggestions and are finalizing definitions consistent with our proposal.

(Comment 12) One comment recommends that we specify that the "local farmers" at a farmers' market be from within the same state as the point of sale or within 275 miles of the point of sale. However, most of the comments that addressed our request for comments on distance limitations for farmers' markets and roadside stands expressed concern about any such limitations. Some comments state there should be no distance limitation because the distance from a farm to a roadside stand or farmers' market does not change the fact that the food is being provided directly to consumers. Some comments state that there is no established public health risk related to the distance between a farm and sales locations such as farmers' markets and roadside stands. One comment states that there is no risk-based justification for including distance limitations in the definitions for farmers' markets and roadside stands. Comments also note it is not uncommon for farms to locate stands or take part in farmers' markets in metropolitan areas where they are likely to interact with and have more ready access to a larger customer base, and that these metropolitan areas are removed from the rural areas where growing takes place. Comments also state that grocery stores and other entities that identify as retail food establishments have no mileage limitations connected to their headquarters, so there should be no reason to apply such a distinction to similarly situated businesses.

(Response 12) FDA agrees with the comments recommending against distance limitations in the definitions for farmers' markets and roadside stands. In enacting section 102(c) of FSMA, Congress directed FDA to clarify that in determining the primary function of an establishment, the sale of food directly to consumers by such establishments includes the sale of food at a roadside stand or farmers' market, where such stand or market is located other than where the food was manufactured or processed. Section 102(c) of FSMA does not provide a limitation on distance, and we decline to add such a limitation on our own accord.

3. Sale and Distribution of Food Through a Community Supported Agriculture Program

(Comment 13) One comment urges FDA to define CSAs as involving the sale of "food" rather than "crops," as we proposed. The comment states that CSAs may involve the distribution of food other than crops.

(Response 13) FDA agrees that CSA activities are not limited to only selling "crops." For example, a farm mixed-type facility may sell strawberries it grows and strawberry jam that it manufactures directly to consumers through a CSA. Whether the on-farm manufacturing establishment is a retail food establishment, and thus exempt from registration, would depend on whether its primary function is to sell food directly to consumers.

As to whether we should change the proposed definition of CSAs to refer to "food" instead of "crop(s)," we do not believe such a change is warranted. Section 102(c) of FSMA provides that for the purposes of the retail food establishment definition, "the term 'community supported agriculture program' has the same meaning given the term . . . in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation)." Because 7 CFR 249.2 refers to "crop(s)," not "food," we do not believe that the change suggested by the comments would be consistent with section 102(c) of FSMA. However, the sale of food directly to consumers through a platform that resembles a CSA but does not sell crops could still be used in determining the establishment's primary function in the final rule. Paragraphs (1)(iii) and (2)(iii) of the retail food establishment amendment are catchalls that include the sale of food at other direct-to-consumer platforms. Provided that the requirements of those paragraphs are satisfied, an establishment could consider sales through that platform in determining its primary function if either the establishment is: (1) Located on a farm; or (2) is a farm-operated business and the requirements applicable to farm-operated businesses are met.

4. Sale and Distribution of Food at Any Other Direct-to-Consumer Sales Platforms

(Comment 14) Most comments agree with the list of direct-to-consumer platforms that we proposed. One comment, however, states that FDA should not consider as direct-to-consumer sales those sales by mail, catalog or Internet order, or through online farmers' markets or online grocery delivery. The comment states that allowing these types of sales creates an opportunity for an on-farm manufacturing operation that sells large volumes of food in interstate commerce to fall within the retail food establishment definition. The comment further states that a common feature of sales at roadside stands, farmers' markets, and CSAs listed in section 102(c)(1) of FSMA is that they are conducted face-to-face and it is likely that Congress meant to provide FDA with flexibility to consider as direct-to-consumer sales other local face-to-face transactions that are similar to the specified exempt activities, but not platforms such as direct-to-consumer mail, catalog, or Internet sales that would allow for national sales.

(Response 14) We agree that section 102(c) of FSMA directs FDA to address certain direct-to-consumer sales in clarifying the retail food establishment definition. However, we disagree with the objection to including the sale of food through mail, catalog and Internet orders, including online farmers' markets and online grocery delivery, in determining the primary function of an establishment that is either located on a farm or that is a farm-operated business. As discussed in the proposed rule (80 FR 19160 at 19166), these direct sales platforms are common platforms for direct-to-consumer sales of foods from farms. Although such sales might not be face-to-face, direct-to-consumer sales of food from local farms and establishments closely associated with farms are similar to farmers' markets and CSAs because they are direct-to-consumer. We think that including these direct-to-consumer sales is consistent with section 102(c) of FSMA because section 102(c) provides that the sales of food directly to consumers for the purposes of determining an establishment's primary function may be at "any other such direct sales platform as determined by the Secretary." Section 102(c) of FSMA does not specify that direct-to-consumer sales be face-to-face in determining the primary function of an establishment. Even if some establishments that use mail, catalog, and Internet orders in determining their primary function are larger establishments and can reach consumers on a national level, we do not believe that is inconsistent with section 102(c) of FSMA, which does not specify that FDA's amendment to the retail food establishment definition only pertain to establishments of a specific size. We believe that if an establishment's annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products directly to all other buyers, the establishment's primary function is to sell food directly to consumers and that the establishment should qualify as a retail food establishment. Further, we note that, in determining whether an establishment is a retail food establishment, our regulation has always allowed for establishments selling food directly to consumers via the Internet or mail order to be covered under the definition of "retail food establishment," provided that they meet the other criteria of the retail food establishment definition (see 68 FR 58894 at 58914 to 58915).

(Comment 15) Some comments urge FDA to include "produce auctions" in the list of platforms where direct-to-consumer sales take place.

(Response 15) Because the list of direct-to-consumer sales platforms is not exhaustive, we do not agree that it is necessary to include produce auctions in the list of direct-to-consumer platforms that may be used in determining an establishment's primary function. Provided that a sales platform is direct-to-consumers, sales made through such platforms may help establish that an establishment's primary function is to sell food directly to consumers (with an establishment qualifying as a retail food establishment only if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers). Furthermore, we understand that sales at produce auctions can be to different types of entities. In some cases, sales may be to consumers. However, we understand that many sales at produce auctions are sales to restaurants, wholesalers and other businesses. An establishment's direct sales to individual consumers at an auction can be counted as sales to consumers. A direct sale to a business at an auction, however, cannot be counted as sales to consumers. Further, a direct sale to a separate business that runs a produce auction, rather than to specific buyers, would not be counted as sales to consumers because businesses (including businesses that run produce auctions) are not consumers. Section 102(c)(2) of FSMA explicitly states that the term "consumer" does not include a business.

(Comment 16) Comments request that FDA specifically exempt produce auctions from the requirements of food facility registration. These comments state that produce auctions are frequently misunderstood to be "food facilities," but that they are in fact very similar to farmers' markets in that the auction does not take individual ownership of any products or manufacture/process, hold, pack or package food. The comments note that buyers represent a mix of direct consumers and commercial business entities.

(Response 16) We decline the request to exempt produce auctions from the requirement to register. The registration requirement applies to all facilities that manufacture/process, pack, or hold food for consumption in the United States, and does not hinge on whether the establishment in question actually owns the food (see section 415(a)(1) of the FD&C Act). We note, however, that not all produce auctions will necessarily be required to register. Whether registration is required would depend on the facts of a particular case. It is possible that some produce auctions would qualify as retail food establishments and therefore be exempt from registration. Produce auctions would qualify as retail food establishments if their primary function is to sell food directly to consumers. Produce auctions with direct-to-consumer sales that exceed sales to businesses would be considered retail food establishments. Further, as stated in the final rule for "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food" (80 FR 55908 at 55992), to the extent that these operations are simply a location for buyers and sellers to meet and to sell and transfer produce and the food is not stored, we do not consider such facilities to be holding food and would not expect them to register.

(Comment 17) Some comments request that we expand the list of direct-to-consumer platforms that we proposed to specify to also include food hubs, buying clubs, and non-farm community supported food distribution models.

(Response 17) We decline to revise the retail food establishment definition in § 1.227 to specifically discuss food hubs, buying clubs, and non-farm community supported distribution models. With respect to food hubs, the comments do not explain why food hubs necessarily involve direct-to-consumer sales that should be used in determining an establishment's primary function. FDA discussed food hubs in the final preventive controls for human food regulation (see 80 FR 55908 at 55992). As FDA noted in that rulemaking, USDA defines a regional food hub as "a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand" (Ref. 7). Some food hubs have a farm-to-business model (*e.g.,* selling to food cooperatives, grocery stores, institutional foodservice companies, and restaurants), while others have a farm-to-consumer model (*i.e.,* selling directly to the consumer, *e.g.,* through a CSA), and some are hybrids that do both (Ref. 7). Because all sales at food hubs are not necessarily direct-to-consumer, we do not agree that it is appropriate to include food hubs in the list of direct-to-consumer platforms that may be used in determining an establishment's primary function. However, if an establishment located on a farm or an establishment described in paragraph (2) of the retail food establishment definition has food hub sales that are directly to consumers, we agree that, in those circumstances, it would be appropriate for those sales to be used in determining the establishment's primary function. The catchall provisions in paragraphs (1)(iii) and (2)(iii) of the definition provide that the sale of food directly to consumers includes the sale and distribution at other direct-to-consumer platforms. For similar reasons, we do not agree that it is appropriate to amend the retail food establishment definition to include buying clubs and non-farm community supported food distribution models. The comments have not provided information to allow FDA to assess whether such platforms necessarily involve direct-to-consumer sales. However, if on-farm establishments or establishments described in paragraph (2) have sales at such platforms that are directly to consumers, the sales may also be used in determining those establishments' primary function in accordance with paragraphs (1)(iii) and (2)(iii).

5. Other Issues Related to the Definition of Retail Food Establishment

(Comment 18) One comment states that there should not be any income or value limitation included in the retail food establishment definition.

(Response 18) We agree that there is no income limitation for establishments to qualify as retail food establishments, and we have not included one in the final rule. As long as an establishment's primary function is to sell food directly to consumers, it is a retail food establishment. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(Comment 19) One comment urges FDA to recognize that even low-risk activities can cause problems and recommends limiting the application of section 102(c) of FSMA to the types of on-farm manufacturing activities that the Agency tentatively identified as low-risk activities in proposed 21 CFR 117.5(g) and (h) in the proposed regulation for hazard analysis and risk-based preventive controls for human food. This is based on the argument that section 102(c) of FSMA, which directed FDA to clarify the retail food establishment definition, should be read in connection with section 103(c)(1) of FSMA, which formed the basis for proposed § 117.5(g) and (h). Specifically, section 103(c)(1) of FSMA directed FDA to conduct a science-based risk analysis of specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as well as of specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership. Section 103(c)(1) of FSMA further directed FDA to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 of the FD&C Act (related to risk-based preventive controls) and section 421 of the FD&C Act (related to targeting of inspection resources) for small and very small businesses, or modify those requirements for small and very small businesses. In addition, the comment recommends that the amendment to the retail food establishment definition should only apply to small and very small farms, as defined in the proposed regulation for produce safety. The comment states that Congress intended for the retail food establishment amendment to only apply to small and very small farms, as evidenced by certain statements made on the Senate floor regarding small farmers.

(Response 19) Consistent with the statutory direction in section 103(c) of FSMA, including the direction to conduct a qualitative risk assessment, FDA established exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses in the final rule for preventive controls for human food (§ 117.5(g) and (h)). We do not agree that section 102(c) of FSMA, which directed FDA to clarify the retail food establishment definition, should be read to only apply to entities that qualify for the exemptions we established in accordance with section 103(c) of FSMA. Congress's direction in section 102(c) of FSMA to amend the definition of retail food establishment was separate and distinct from Congress's direction in section 103(c) of FSMA to establish exemptions and modifications for certain on-farm activities, and we are not aware of any evidence that Congress intended for the amendment to the retail food establish definition to be limited by the entities that qualify for exemptions in accordance with section 103(c) of FSMA. As to the comment that the amendment to the retail food establishment definition should only apply to small and very small farms, we similarly do not agree. Section 102(c) of FSMA does not provide that the determination of the primary function be different for establishments of particular sizes. Although there is some legislative history indicating that some legislators anticipated that the amendment would affect small enterprises, we are not aware of evidence that Congress intended for the amendment to only apply to smaller enterprises, and there is no such limitation in the statutory provision. Moreover, we believe it is appropriate to apply the same primary function analysis to all establishments regardless of size, with an establishment's primary function being to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(Comment 20) One comment states that our amendment to the retail food establishment definition should incorporate a method to evaluate potential risks to allow the Agency to determine if the establishment has food safety issues or is subject to proper oversight.

(Response 20) We decline this request. The comment does not explain how FDA would evaluate potential risks or what kind of food safety and/or oversight criteria the Agency would apply. Further, the comment does not explain how the request would be consistent with section 102(c) of FSMA. That provision, which directs FDA to clarify the retail food establishment definition, does not state that the clarification to the definition should involve FDA performing any kind of risk evaluation of individual establishments.

(Comment 21) One comment states that our amendment to the retail food establishment definition should consider off-farm sales to businesses in the primary function calculation, and not just consumers. The comment states that similar to the determination for whether an entity is a qualified farm under the produce safety regulation or a qualified facility under the preventive controls regulations, the determination for whether an establishment is a retail food establishment should consider sales to "qualified end users." Another comment states that the amendment to the definition should only consider sales at "the retail distribution level directly to consumers[.]"

(Response 21) We disagree with the comment requesting that sales to businesses be included in the primary function calculation, and agree with the comment that the amendment should only consider sales "at the retail distribution level directly to consumers" to the extent that comment requests that the primary function calculation only include direct-to-consumer sales. Section 102(c)(2)(B) of FSMA provides that the term "consumer" does not include a business, and we think it is consistent with that provision to establish that sales to consumers do not include sales to businesses for the purpose of determining an establishment's primary function. It is true that the preventive controls and produce safety regulations provide for certain specified businesses to be qualified end-users. Under the preventive controls regulations, qualified end-users include restaurants or retail food establishments located in the same State as the qualified facility that sold the food to such restaurant or establishment or are not more than 275 miles from such facility or farm and are purchasing the food for sale directly to consumers at such restaurant or retail food establishment. Under the produce safety regulation, a qualified end-user includes a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food or not more than 275 miles from such farm. Whether a facility or farm sells food directly to a qualified end-user is significant under the preventive controls and produce regulations because sales to qualified end-users may be used in determining whether facilities or farms are eligible for qualified exemptions under those regulations. Although sales to qualified end-users are significant under those regulations, we do not agree that sales to such qualified end-users that are not consumers should be used in determining an establishment's primary function as a retail food establishment for the purposes of registration. Congress specified that qualified end-users include certain restaurants and retail food establishments for purposes of the preventive controls and produce safety regulations (see sections 418(l)(4)(B) and 419(f)(4)(A) (21 U.S.C. 350h(f)(4)(A)) of the FD&C Act), but specified that for purposes of amending the retail food establishment definition the term "consumer" does not include businesses (see section 102(c)(2)(B) of FSMA).

B. U.S. Agent

We proposed to amend the definition of U.S. agent in § 1.227 to add that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

In addition, we proposed to replace the word "cannot" in the current definition for U.S. agent in § 1.227 with "may not." Accordingly, the pertinent sentence in that provision will provide that, "A U.S. agent *may not* be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present" (emphasis added).

(Comment 22) Comments state that it is confusing to distinguish the U.S. agent for food facility registration and the U.S. agent for purposes of the foreign supplier verification program ("FSVP") requirements under 21 CFR part 1, subpart L, and urge FDA to include language in the registration final rule that clarifies that the U.S. agent for purposes of food facility registration and the U.S. agent for purposes of FSVP are not the same and must be designated through separate procedures.

(Response 22) We do not agree that any amendments to the regulatory text of the final rule are necessary. Section 805(a)(2)(B) of the FD&C Act (21 U.S.C. 384a(a)(2)(B)),which pertains to FSVP, provides that when there is no U.S. owner or consignee with respect to an article of food at the time of entry of the article into the United States, the term "importer" for purposes of FSVP requirements means "the *United States agent* or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States" (emphasis added). Under the FSVP final rule, the "importer" is responsible for verifying the safety of food imported into the United States. In addition, section 415(a)(1)(B) of the FD&C Act provides that foreign food facilities must submit the name of the "United States agent" for the facility as part of the facility's registration under section 415. FDA's regulations implementing the food facility registration requirements in section 415 of the FD&C Act require that the registration for foreign facilities must include the name of the U.S. agent for the facility (21 CFR 1.232(c)(1)). The facility registration regulations also define the term U.S. agent to mean a person (as defined in section 201(e) of the FD&C Act) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of food facility registration (§ 1.227). The regulations further specify that the U.S. agent "acts as a communications link between FDA and the foreign facility for both emergency and routine communications" (§ 1.227).

Although Congress used the term "United States agent" in both section 805(a)(2)(B) and section 415(a)(1)(B) of the FD&C Act, we do not interpret the use of the term "United States agent" in section 805(a)(2)(B) to mean the U.S. agent for a foreign facility under section 415(a)(1)(B). U.S. agents that foreign food facilities must designate for purposes of food facility registration perform a very different role than the "United States agent" that a foreign owner or consignee may designate under section 805(a)(2)(B) of the FD&C Act to serve as the "importer" for purposes of the FSVP regulations. For food facility registration, the "U.S. agent" acts as a communications link. For FSVP, however, an importer (whether a "United States agent" or otherwise) is responsible for the full breadth of supplier verification activities required under the FSVP regulation. These activities involve ensuring the safety of imported food, which is qualitatively different from serving as a communications link (80 FR 74226 at 74241; November 27, 2015). Thus, we do not interpret the use of the term "United States agent" under section 805(a)(2)(B) to have the same meaning as the U.S. agent that food facilities are required to designate under section 415(a)(1)(B) and FDA's food facility registration regulations. As we state in the FSVP final rule, however, this interpretation does not prohibit a foreign owner or consignee from designating a person who serves as a U.S. agent under the food facility regulations as the "importer" for purposes of FSVP (Id.).

Because we do not interpret the use of the terms to have the same meaning, we do not think it is necessary to add regulatory text in this final rule stating that the U.S. agent for purposes of food facility registration is not the same as the U.S. agent for purposes of the FSVP final rule. Additionally, we think such language could be confusing because there is no prohibition on the same person serving as both the U.S. agent for purposes of food facility registration and the U.S. agent for purposes of satisfying the FSVP "importer" requirements (provided that such person meets the relevant requirements of each regulation).

(Comment 23) Comments request FDA clarify that the communications link between the U.S. agent and FDA goes both ways and that FDA also clarify that communications to and from the U.S. agent have the same legal effect as if sent to or by the facility directly for both routine and emergency communications.

(Response 23) As established in current § 1.227, the U.S. agent acts as a communications link between FDA and a foreign facility for both routine and emergency communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact. In functioning as the communications link with FDA, a U.S. agent may choose to initiate communications with FDA, and FDA may likewise choose to initiate communications with the U.S. agent. Further, as stated in § 1.227, FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. In that sense, information or documents provided to the U.S. agent has the same effect as if FDA provided the information or documents to the foreign facility, in that FDA will consider providing information or documents to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(Comment 24) One comment requests FDA outline and clarify the roles and responsibilities of the U.S. agent.

(Response 24) The roles and responsibilities of a U.S. agent are outlined in current § 1.227. As stated previously, the U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications.

(Comment 25) Comments request that FDA clarify that the U.S. agent for a foreign food facility may access the facility's FDA Unified Registration and Listing Systems (FURLS) and help desk on behalf of the foreign facility, and that the U.S. agent should have access to Form FDA 483s and Establishment Inspection Reports (EIR) pertaining to the foreign facility.

(Response 25) The final rule provides that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. The U.S. agent will be able to view the information electronically via FURLS Food Facility Registration Module, in the interim, U.S. agents may contact FDA's help desk with questions about foreign facilities that they represent. In addition, a U.S. agent may contact FDA's help desk on behalf of the foreign facility. As to whether U.S. agents may have access to any Form FDA 483s and EIRs related to the foreign facility, certain information (such as confidential commercial information and trade secret information) in such records is protected from disclosure. FDA also generally does not proactively make available information related to FDA inspections of facilities, including FDA Form 483s and EIRs, although it is possible that a U.S. agent could obtain such information from the foreign facility or from FDA through a FOIA (5 U.S.C. 552) request. Any confidential commercial information, trade secret information, or other protected information in FDA Form 483s and EIRs that we provide through a FOIA request would be redacted (*i.e.,* deleted) in accordance with the disclosure exemptions set forth in the FOIA and 21 CFR part 20.

V. Comments on Proposed Amendments to § 1.230—When Must You Register or Renew Your Registration?

A. Proposed § 1.230(a)—When Must You Register?

We proposed to delete the reference to the December 12, 2003, deadline in current § 1.230(a) and instead require that owners, operators, or agents in charge must register before the facility begins to manufacture, process, pack, or hold food for consumption in the United States. We did not receive any comments on this change and are finalizing as proposed.

B. Proposed § 1.230(b)—Registration Renewal

We proposed amending § 1.230 to require biennial registration renewal and provide for an abbreviated registration renewal process. Proposed § 1.230(b) would require that during the period beginning on October 1 and ending on December 31 of each even-numbered year, the owner, operator, or agent in charge of a facility would be required to submit a registration renewal to FDA containing the information required under § 1.232. Under proposed § 1.230(b), the owner, operator, or agent in charge of a facility would be able authorize an individual to renew the facility's registration on its behalf. We proposed that if the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration renewal, and identifies by name, address, email address, and telephone number, the individual who authorized submission of the registration renewal. We proposed that each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option).

We are finalizing these requirements, with two modifications. First, we have modified the proposed requirement to provide the email address for the individual who authorized submission of the registration renewal if the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility. For registration renewals not submitted by the owner, operator, or agent in charge, final § 1.230(b) provides that the registration renewal must identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under § 1.245. Registration renewals not submitted by the owner, operator, or agent in charge must also identify by name, address, and telephone number the individual who authorized the submission, as proposed. Second, we have added a requirement that each electronic registration renewal must include the name of the individual submitting the renewal. We have made this change because we believe that this information will aid our ability to verify that the individual submitting the registration information is authorized to do so.

(Comment 26) A comment states a concern with the potential for a bottleneck or system overload during the October 1 to December 31 registration renewal period. The comment asks if FDA would consider a biennial renewal expired if it was properly submitted on or prior to the December 31 deadline but was not timely administered or accepted by FDA on or prior to the December 31 deadline. The comment also requests that FDA consider extending the biennial registration deadline so that properly and timely submitted biennial renewals are not considered expired if FDA has not administered or accepted the facility's submission.

(Response 26) Beginning with the first biennial registration renewal period in 2012, information technology (IT) capabilities were added to support the system to help prevent any system failure or overload. FDA will continue this protocol during all biennial registration renewal periods to ensure that our IT systems can operate during high-traffic times. Given these IT investments, FDA does not anticipate that IT failures will cause problems with our registration system administering or accepting submissions during the registration renewal period. However, if any technical problems do arise during the biennial registration renewal period, FDA may consider extending the time period for biennial registration renewals, for instance by providing registrants at least the same number of calendar days for biennial registration renewal as allowed for under the FSMA amendments to section 415 of the FD&C Act. During the first biennial renewal period in 2012, FDA took such an approach. At that time, there was a delay with the registration renewal period becoming operational and FDA extended the deadline for facilities to complete renewals. As to the concerns regarding expired registrations, as discussed in section XI of this document, we are adding § 1.241(b) to specify that FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). If a food facility registration or renewal registration is submitted (or postmarked for paper submissions) on or before the renewal deadline and includes all required information, we will not consider such a registration to be expired. As described in section XI of this document, § 1.241(c) provides that FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). For registrations that we do not consider to be expired, we will not cancel the registrations under § 1.241(c). In addition, in the event that any IT problems complicate the submission and receipt of registration renewals, we would take that into account in determining whether to consider any registrations to have expired.

Prior to the beginning of the biennial registration renewal period on October 1, FDA intends to send an email to all registrants and U.S. agents notifying them of the upcoming registration renewal period. In these emails, we plan to provide information about the deadline for registration renewal. Once the renewal period begins, if a registrant has not submitted a renewal, we plan to continue to send emails reminding registrations of the upcoming deadline through the end of the registration renewal period on December 31.

C. Proposed § 1.230(c)—Abbreviated Registration Renewal Process

Under proposed § 1.230(c), we proposed to provide for an abbreviated registration renewal process for registrations that do not have any changes to the information required under § 1.232 since the submission of the preceding registration or registration renewal. The abbreviated registration renewal process that we proposed would require a registrant to confirm that no changes have been made to the information required in the registration since the registrant submitted the preceding registration or registration renewal, confirm that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act, and certify that the information submitted is truthful and accurate. FDA also proposed that registrants must use Form FDA 3537 to submit abbreviated registration renewals to FDA. In response to some comments, we have made some changes to these requirements.

In addition, on our own initiative, we have changed § 1.230(c) to require that each abbreviated renewal include the name of the individual making the submission and the individual's signature (for the paper option). We have made this change because we believe that this information will aid our ability to verify that the individual submitting the registration information is authorized. We have also changed § 1.230(c) to require that for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under § 1.245. We made this change in order to enable us to more efficiently perform the verification process established in § 1.231(a)(4) and (b)(6) for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility. Under those provisions, after submission of the abbreviated renewal (whether submitted electronically or by mail or fax), FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the abbreviated renewal until that individual confirms that he or she authorized the submission. Having the email address for the individual who authorized submission of the registration renewal will enable us to more quickly and efficiently conduct the verification so that we can more quickly provide confirmation of the renewal. Finally, we have changed § 1.230(c) to allow food facilities to submit abbreviated registration renewals if the information required in the registration has not changed since the facility submitted an update or since the facility submitted the preceding registration or registration renewal. Under the proposed rule, the abbreviated option would only have been available if no information changed since the facility submitted the preceding registration or registration renewal. We made this change so that food facilities will not be required to complete the standard renewal process if the required information is unchanged since the facility's most recent registration update. We believe that this change will make the renewal requirement less burdensome for food facilities.

Furthermore, we note that we consider abbreviated renewals to be included as part of the registration renewal process explained in § 1.231 of the final rule.

(Comment 27) Comments recommend FDA simplify its proposal for "abbreviated" renewals by requiring only that a box be checked to confirm that there have not been any changes to the registration information previously submitted, including to the previously submitted certification regarding the truthfulness and accuracy of the registration information.

(Response 27) We agree that registrants submitting abbreviated registration renewals need not confirm that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. We believe that the requirement in the final rule in § 1.230(c) that registrants confirm that no changes have been made to the information required under § 1.232 since the preceding registration or registration renewal encompasses a confirmation regarding FDA being permitted to inspect. Accordingly, we have revised § 1.230(c) in the final rule to no longer require that abbreviated registration renewals provide confirmation regarding FDA being permitted to inspect. However, we continue to believe that it is appropriate for abbreviated registration renewals to certify that the information submitted is truthful and accurate. We believe such certifications will help deter individuals from submitting false information, including falsely certifying that no changes have been made to the required information. For the reasons discussed in the previous paragraphs, we also believe it is appropriate for abbreviated renewals to include the name of the individual submitting the renewal and, for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized the submission.

VI. Comments on Proposed Amendments to § 1.231—How and Where Do You Register or Renew Your Registration?

A. Proposed § 1.231(a)—Electronic Registration and Registration Renewal

In proposed § 1.231(a), we proposed to require mandatory electronic registration and registration renewals beginning January 4, 2016, unless a waiver has been granted under § 1.245. In the proposed rule, we proposed in § 1.245 to provide that to request a waiver from the electronic registration or renewal requirement, a registrant must submit a written request to FDA that explains why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. In the proposed rule, FDA tentatively concluded that reasons for why it may not be reasonable for a registrant to submit a registration or registration renewal to FDA electronically may include conflicting religious beliefs or where a registrant does not have reasonable access to the Internet (80 FR 19160 at 19177 to 19178).

We requested comment on the proposed requirements for mandatory electronic registration and registration renewals to begin in the year 2016 and the proposal to allow for a waiver from these requirements. We also requested comment and data on the number of facilities, if any, that believe they would be unable to register or renew their registrations electronically, and the reasons for such belief.

(Comment 28) One comment states that small foreign facilities may not be able to submit registrations electronically by 2016 because there is no reliable access to the Internet. The comment requests that paper submissions remain an option.

(Response 28) We recognize that there may be a need for additional flexibility regarding the deadline for requiring electronic registrations and registration renewals. In response to this comment, we are revising § 1.231(a)(2) to replace the proposed January 4, 2016, deadline for electronic registrations and registration renewals with a January 4, 2020, deadline. In addition, we are also revising § 1.231(a)(2) to state that registrations or registration renewals must be submitted electronically "unless FDA has granted" a waiver. The proposed provision would have stated that the electronic registration requirement applies "unless you have been granted a waiver." We believe that this change is consistent with § 1.245, which makes clear that the waivers are granted by FDA. Accordingly, final § 1.231(a)(2) provides that owners, operators, or agents in charge must submit their registration or registration renewal to FDA electronically beginning on January 4, 2020, unless FDA has granted a waiver under § 1.245. If FDA has granted a waiver, registrations and registration renewals may be submitted through mail or fax.

B. Proposed § 1.231(b)—Registration or Registration Renewal by Mail or Fax

In proposed § 1.231(b), we proposed that, beginning January 4, 2016, we would allow registrants to submit registration or registration renewals by mail or fax if a waiver has been granted under proposed § 1.245. As we explained in Response 30, we are replacing the January 4, 2016, deadline with a January 4, 2020, deadline.

As revised, final § 1.231(b) states that beginning January 4, 2020, registrants must submit their registrations or registration renewals to FDA electronically, unless FDA has granted a waiver under § 1.245. If FDA has granted a waiver under § 1.245, the registrant may register or renew a registration by mail or by fax. The revisions reflect our decision to delay the requirement to submit registrations electronically until January 4, 2020, and also to be consistent with § 1.245 in making clear that waivers under § 1.245 are granted by FDA.

C. Proposed §§ 1.231(a)(3) and (b)(5) and 1.234(c)(2) and (d)(5)—Unique Facility Identifier and Verification Procedures for FDA

In proposed § 1.232(a)(2), we proposed to require the D–U–N–S number of a domestic and foreign facility be included in the facility's registration. We proposed for this requirement to function in connection with proposed § 1.231(a)(3) and (b)(5), which would provide that after a facility completes its registration or updates its D–U–N–S number as part of registration renewal, FDA would verify the accuracy of the facility's D–U–N–S number and would also verify that the facility-specific address associated with the D–U–N–S number is the same address associated with the facility's registration. Under proposed § 1.231(a)(3) and (b)(5), FDA would not confirm a food facility's registration or registration renewal until FDA verifies the accuracy of its D–U–N–S number and verifies that the facility-specific address associated with the D–U–N–S number is the same address associated with the facility's registration. With respect to initial registrations, proposed § 1.231(a)(3) and (b)(5) would also provide that FDA would not provide a facility with a registration number until FDA verifies the accuracy of its D–U–N–S number and verifies that the facility-specific address associated with the D–U–N–S number is the same address associated with the facility's registration. Proposed § 1.231(a)(3) would apply this verification requirement to electronic registrations, and proposed § 1.231(b)(5) would apply this requirement to registrations submitted by mail or fax. We also proposed for the requirement to submit D–U–N–S numbers to function in connection with proposed § 1.234(c)(2) and (d)(5), which proposed to provide that FDA would perform the same verification step after facilities complete their registration updates. Under proposed § 1.234(c)(2) and (d)(5), FDA would not provide an update confirmation until FDA verifies the accuracy of the food facility's D–U–N–S number and also verifies that the facility-specific address associated with the D–U–N–S number is the same address associated with the facility's registration. Proposed § 1.234(c)(2) would apply this verification requirement to electronic updates, and proposed § 1.234(d)(5) would apply this requirement to updates submitted by mail or fax. As discussed more fully in section VII.B of this document, § 1.232(a) of the final rule requires domestic and foreign facilities to submit a UFI recognized as acceptable to FDA in the facility's registration. We are not finalizing the proposal to include a D–U–N–S number.

(Comment 29) Comments recommend FDA verify registration information with the U.S. agent for foreign facilities rather than using D–U–N–S numbers. The comments state that such a verification process would be less burdensome and complex.

(Response 29) We decline this suggestion. We believe that a verification process that will function in connection with a UFI will be more efficient and effective than relying on the U.S. agent. In addition, only foreign facilities have U.S. agents. Domestic facilities do not have U.S. agents.

(Comment 30) Comments state that users should be given additional attempts to input registration information if the verification step is unsuccessful. Comments also ask how FDA will inform a facility of an unsuccessful UFI verification step and how facilities will be able to correct information.

(Response 30) For electronic registration submissions, the registration screen would immediately notify the food facility if we are unable to verify the UFI or if the facility-specific address associated with the UFI is the same address associated with the registration. For registration submissions by mail or fax, FDA will use the contact information available for the facility to notify the facility of any such occurrence. If FDA is unable to verify the UFI or to verify that the facility-specific address associated with the UFI is the same address associated with the registration, the facility would have the opportunity to fix the information in the registration. However, if it turns out that FDA is unable to verify this information because the UFI provider has incorrect information about the facility, the facility may contact the UFI provider to resolve the discrepancy. If verification problems persist, the facility may contact FDA.

(Comment 31) One comment asks that FDA allow U.S. agents to "search for D–U–N–S numbers of facilities" before a facility registers. The comment states that this will help ensure the accuracy of the registration information submitted to FDA.

(Response 31) To the extent that the comment is asking that U.S. agents be able to search the Dun and Bradstreet database, we will consider this comment when we implement the UFI requirement. Whether U.S. agents may search the database of the UFI system that FDA recognizes as acceptable may depend on a number of factors, including what database information, if any, the UFI provider makes public. If U.S. agents wish to ensure the accuracy of foreign facilities' registration information, they may wish to work with the foreign facilities directly.

(Comment 32) Many comments state that requiring the submission of D–U–N–S numbers will not enhance the accuracy of FDA's registration database. A comment states that a D–U–N–S number cross-check is an additional time-consuming step and is not effective at preventing inaccurate information from being submitted to FDA. One comment states that discrepancies in the FDA database and the Dun and Bradstreet database may cause disruptions and delays in registration.

(Response 32) We disagree with the comments asserting that the UFI verification step will not enhance the accuracy of FDA's registration database. A UFI system such as D–U–N–S will allow the Agency to leverage the information in the UFI system, providing assurance that the address associated with the food facility is accurate. For instance, FDA uses D–U–N–S numbers for drug establishment registration (Ref. 8). FDA has found that the use of D–U–N–S numbers for drug establishment registration has been a useful resource for identifying and verifying certain business information. Regarding concerns about disruptions and delays, we do not anticipate significant problems. We are postponing the requirement for providing a UFI in registrations until the registration renewal period beginning October 1, 2020, which should provide food facilities sufficient time to obtain a UFI. If any facilities encounter delays associated with the UFI requirement or verification step, they may contact FDA.

(Comment 33) Comments recommend using inspection information obtained by FDA investigators during inspections to confirm and verify registration information instead of requiring information about D–U–N–S numbers.

(Response 33) To the extent possible, FDA investigators do confirm the accuracy of food facility registration information when conducting inspections. However, FDA investigators are not able to ensure the accuracy of FDA's registration information in an efficient or comprehensive manner. Due to limited resources, FDA is not able to inspect every registered facility with the frequency needed to ensure that the registration information for any particular facility is accurate at any particular time. Information might change in-between inspections, and inaccurate registration information could hinder FDA's ability to locate facilities for inspection. We believe that requiring a UFI recognized as acceptable to FDA is a more efficient and effective way to help ensure the accuracy and reliability of the registration information and to help ensure that the registration database is up-to-date.

(Comment 34) Comments question the capacity of the registration database to save registrations for completion at a later date so that the registrant can obtain a D–U–N–S number.

(Response 34) FDA's registration system has the needed capacity to save registration information for completion at a later date. While FDA will not save an incomplete registration on the server indefinitely, the information will be stored for a period of time greater than the maximum amount of time needed to acquire a UFI.

(Comment 35) One comment addresses "pharmaceutical wholesale distributors" that hold only a small amount of food. For these facilities, the comment suggests that FDA verify the facility-specific address using means other than a D–U–N–S number. The comment states that the Agency can instead refer to facility-specific information collected by CDER and/or information collected by State licensing authorities.

(Response 35) We do not think it is appropriate to establish different registration requirements for facilities of different sizes or for facilities that manufacture, process, pack, or hold different amounts of food. Food facilities of any size that handle any amount of food may be linked to terrorism attacks or other food-related emergencies. In the event that any attacks or other emergencies occur, it will be important for FDA to have accurate and up-to-date information about all facilities. Even if FDA has certain information about facilities through other regulatory processes, we expect that obtaining a UFI through food facility registration will be a more efficient way for FDA to verify the facility's address. However, we may refer to information collected by other FDA regulatory processes as appropriate.

D. Proposed §§ 1.231(a)(4) and (b)(6), 1.234(c)(3) and (d)(6), and 1.235(c)(3) and (d)(6)—Verification Procedures for Submissions Not Made by the Owner, Operator, or Agent in Charge of the Facility

We proposed in proposed § 1.231(a)(4) and (b)(6) that FDA would email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration to verify that the individual in fact authorized submission of the registration on behalf of the facility if the registration or registration renewal was not submitted by the owner, operator, or agent in charge of the facility. We further proposed that FDA would not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration submission. With respect to registration renewals, under proposed § 1.231(a)(4) and (b)(6), FDA would not provide a confirmation of the registration renewal until the individual confirms that he or she authorized the registration renewal. Under proposed § 1.234(c)(3) and (d)(6), FDA would not confirm a registration update until the individual identified as the owner, operator, or agent in charge who authorized the update confirms that he or she in fact authorized the update on behalf of the facility. In addition, under proposed § 1.235(c)(3) and (d)(6), FDA would not confirm a registration cancellation until the individual identified as the owner, operator, or agent in charge who authorized the cancellation confirms that he or she in fact authorized the cancellation on behalf of the facility. We proposed this verification step to address the problem with unauthorized third party registration submissions discussed in the preamble to the proposed rule (80 FR 19160 at 19171). The unauthorized registrations have resulted both in duplicate registrations for food facilities and registrations for facilities that do not in fact manufacture/process, pack, or hold food for consumption in the United States.

(Comment 36) Comments state that it is not evident that use of email verification will sufficiently prevent unauthorized facility registrations, as an email address can be falsified.

(Response 36) We have revised the regulatory text regarding the verification step in the final rule to no longer specify that FDA will email the owner, operator, or agent in charge to conduct the verification. Instead, the final regulatory text provides that FDA will verify that the individual identified as having authorized the submission in fact authorized the applicable submission on behalf of the facility. We have made this change in final §§ 1.231(a)(4) and (b)(6) (for registrations and registration renewals), 1.234(c)(3) and (d)(6) (for updates), and 1.235(c)(3) and (d)(6) (for cancellations). We plan to issue guidance providing more detailed information about how FDA will conduct this verification step. It is possible that the guidance will provide for using email, phone, U.S. mail, or other methods, as appropriate. In determining what methods are appropriate for conducting the verification, FDA will consider the effectiveness of the method for preventing unauthorized registrations. The final rule continues to provide in §§ 1.231(a)(4) and (b)(6) that FDA will not confirm a registration or registration renewal or provide a registration number until the individual confirms that he or she authorized the submission. For updates and cancellations, the final rule continues to provide in §§ 1.234(c)(3) and (d)(6) (for updates), and 1.235(c)(3) and (d)(6) (for cancellations) that FDA will not provide a confirmation of the registration update or cancellation until the individual confirms that he or she authorized the submission.

(Comment 37) Comments suggest that instead of the proposed verifications step, FDA run cross-checks in the food facility registration database to determine if a facility is registered multiple times. These comments argue that contacting the owner, operator, or agent in charge of a facility to verify a registration can be burdensome, especially for owners, operators, or agents in charge of multiple facilities. Comments further suggest FDA run cross-checks in the database to identify submissions for companies with information that does not appear consistent (*e.g.*, different email suffix used, different phone numbers) to identify fraudulent third-party registrations. Other comments encourage FDA to conduct the verification process only after the registration has been submitted. The comments state that this will prevent delays in the registration process.

(Response 37) Due to a large number of registrations and limited resources, it is not possible for FDA to individually monitor every registration and contact every facility outside of the processes provided in the final rule. Under the final rule, if the registration submission is not made by the owner, operator, or agent in charge, we will confirm that the individual identified as having authorized a registration submission in fact authorized the submission. We will provide guidance about how we will conduct this verification step, which may provide for emailing the individual identified as having authorized the submission. Any such process that we outline in guidance will be aimed at ensuring the accuracy of the verification process, while also being efficient and not unduly resource-intensive. Conducting across-the-board surveillance of each registration, by contrast, would demand extensive resources. However, FDA will continue its current practice of individually contacting facilities if specific questions arise regarding the facility's registration. Regarding the request to conduct the verification later in the registration process, we decline that request. We believe that delaying confirmation of the registration submission until after we complete the verification will help deter individuals from submitting unauthorized registrations.

(Comment 38) Several comments suggest that FDA provide the owner, operator, or agent in charge an identification number that they can give to authorized personnel submitting registration, renewals, updates, and cancellations, similar to the VIS for U.S. agents.

(Response 38) We will consider in the future whether to create an identification number to provide to the owner, operator, or agent in charge as suggested in the comments.

E. Proposed §§ 1.231(a)(5) and (b)(7) and 1.234(c)(2) and (d)(5)—Verification Procedures for U.S. Agents

We proposed in § 1.231(a)(5) and (b)(7) that FDA will email the person identified as the U.S. agent for the foreign facility, using the email address for the person identified as the U.S. agent, to verify that the person agreed to serve as the U.S. agent. We further proposed that FDA would not confirm the registration or provide a registration number until that person confirms that the person agreed to serve as the U.S. agent for the facility. In addition, we proposed a similar process for emailing the U.S. agent when foreign facilities update U.S. agent information in proposed § 1.234(c)(2) and (d)(5). Specifically, we proposed that when foreign facilities update the U.S. agent information as part of registration renewal, FDA would not confirm the registration renewal until the person confirms having agreed to serve as the U.S. agent. We also proposed that for registration updates, we would not provide an update confirmation until that person confirms having agreed to serve as the U.S. agent.

In the final rule, we are continuing to require a verification step for U.S. agent information. However, we have revised the regulatory text regarding the verification step to no longer specify that FDA will email the person listed as the U.S. agent to conduct the verification. Instead, the final regulatory text provides that FDA will verify that the person identified as the U.S. agent for the foreign facility agreed to serve as the U.S. agent. We have made this change in final §§ 1.231(a)(5) and (b)(6) (for registrations and registration renewals) and 1.234(c)(2) and (d)(5) (for updates). We plan to issue guidance providing more detailed information about how FDA will conduct this verification step. It is possible that the guidance will provide for using email. The final rule continues to provide in § 1.231(a)(5) and (b)(7) that FDA will not confirm a registration or registration renewal or provide a registration number until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent. For updates, the final rule continues to provide in § 1.234(c)(2) and (d)(5) that FDA will not provide a confirmation of the registration update until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent.

(Comment 39) One comment suggests that the verification email sent to the U.S. agent should include a statement where the U.S. agent affirmatively acknowledges that the U.S. agent may be liable for fees for reinspection costs.

(Response 39) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. See 21 CFR 1.227. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact. See id. Under the final rule, FDA will verify that the person identified as the U.S. agent for foreign facilities has agreed to serve in that role. FDA will not confirm the registration or provide the facility with a registration number until that person confirms that the person agreed to serve as the U.S. agent. See 21 CFR 1.231(a)(5); 21 CFR 1.231(b)(7). In addition, for registration updates, FDA will not provide an update confirmation until the person identified as the U.S. agent confirms that the person agreed to serve as the U.S. agent for the foreign facility. See 21 CFR 1.234(c)(2); 21 CFR 1.234(d)(5). We have revised the regulatory text for the final rule to no longer specify that FDA will email the person listed as the U.S. agent to conduct the verification. Instead, we plan to issue guidance with information about how FDA will verify that the person identified as the U.S. agent agreed to serve in that role. We have not decided on what language we will use in any communications to the person identified as the U.S. agent, whether those communications are conducted using email or through other means. We will consider this comment as we work to implement the U.S. agent verification step.

F. Proposed § 1.231(a)(6) and (b)(9)—Requirement to Update Incorrect Registration Information

We proposed in § 1.231(a)(6) and (b)(9) that if any information previously submitted was incorrect at the time of submission, the registrant must immediately update the facility's registration as specified in § 1.234. We did not receive any comments on these provisions and are finalizing the provisions as proposed.

VII. Comments on Proposed Amendments to § 1.232—What Information Is Required in the Registration?

We proposed in § 1.232(b)(1) to codify in FDA's registration regulation the requirement of section 415(a)(2) of the FD&C Act that a registration for a domestic facility contain the email address for the contact person of the facility. This requirement went into effect upon enactment of FSMA. In proposed § 1.232(c)(1), we also proposed to codify the requirement of section 415(a)(2) of the FD&C Act that a registration for a foreign facility contain the email address of the U.S. agent for the foreign facility. This requirement also went into effect upon enactment of FSMA.

In addition, we also proposed to require that a food facility registration include the email address of the owner, operator, or agent in charge, and that registrations include the D–U–N–S number of a domestic and foreign facility be included in the facility's registration. We further proposed to require the type of activity conducted at the facility for each food product category defined. We proposed that facilities choose among the following activity types: (1) Ambient human food storage warehouse/holding facility; (2) Refrigerated human food warehouse/holding facility; (3) Frozen human food warehouse/holding facility; (4) Interstate conveyance caterer/catering point; (5) Contract sterilizer; (6) Labeler/relabeler; (7) Manufacturer/processor; (8) Farm mixed-type facility; (9) Packer/repacker; (10) Salvage operator (reconditioner); (11) Animal food warehouse/holding facility; (12) Other activity. Facilities would be permitted to select more than one activity type for each food product category identified. The "Other Activity" option would only be available if the facility engages in an activity that is not covered by the other options. Facilities that select "Other Activity" would be required to enter text onto the food facility registration form describing the activity. Although we proposed to specify the specific activity types that food facilities must select, we did not propose to define those activity types. Instead, we requested comments on whether we should do so, and also requested comments on possible definitions. We further sought comment on whether processing of thermally processed low-acid foods packaged in hermetically sealed containers ("LACF") and acidified foods should be treated as activity types, or whether there should be food product category options related to low-acid canned foods and acidified foods, or both.

We further proposed to update the registration regulation regarding food product categories.

The rule also proposed to codify in FDA's registration regulation the requirement for food facility registrations to include a statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. This requirement went into effect upon enactment of FSMA.

The rule further proposed certain changes related to registrations not submitted by the owner, operator, or agent in charge of the facility. Currently, § 1.232(i) provides that if the individual submitting the registration form is not the owner, operator, or agent in charge of the facility, the registration must include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. We proposed to recodify this provision in proposed § 1.232(a)(10), and also to add the email address of the individual who authorized submission of the registration to the list of required information identifying the individual who authorized submission of such registrations.

In addition, we proposed to require domestic facilities (proposed § 1.232(b)(2)) provide an emergency contact phone number and an email address if the email address is different from the facility contact person email address required in proposed § 1.232(b)(1). For foreign facilities, we proposed to require (in § 1.232(c)(2)) that the foreign facility provide an emergency contact number and email address. Further, we proposed to retain the requirement in current § 1.232(g) (proposed § 1.232(a)(7)) that food facilities provide information regarding food product categories, but to change that requirement to be consistent with the changes FDA has made to food product categories in response to the FSMA amendments.

A. Requirement for Certain Email Address Information

(Comment 40) Comments state that requiring email addresses for the emergency contact of a domestic facility and a foreign facility will not be effective if the email address is for a third party other than the facility. Some comments recommend that the rule should be amended so that food facilities can indicate their preferred means of contact in an emergency on the registration form, whether by email, phone, fax or other.

(Response 40) We believe that having the required email addresses will assist FDA in responding to food-related emergencies even when the email address is for a third party, and therefore disagree with the comments suggesting otherwise. Email is a fast and efficient method to communicate, and we anticipate that having the email address for the emergency contact for a domestic facility and foreign facility will assist us in reaching those contacts. Regarding the request to allow facilities to indicate their preferred means of contact during an emergency (*e.g.*, email, phone, fax, or other), we will consider whether to add an optional field on Form FDA 3537 that would allow facilities to indicate this. If we add any such optional field, we will issue guidance in accordance with our GGP regulations in 21 CFR 10.115.

(Comment 41) A comment opposes having to provide an email address for the U.S. agent in addition to the name, full address, and phone number of the U.S. agent. The comment states that a U.S. agent's email address will be of little assistance to FDA during an emergency because once submitted, the contact information could change and may never be updated.

(Response 41) Section 415(a)(2) of the FD&C Act, as amended by section 102(a) of FSMA, requires, among other things, that a registration for a foreign facility contain the email address of the U.S.

agent for the foreign facility. This requirement went into effect upon enactment of FSMA. Section 1.232(c)(1) of the final rule will codify the requirement in FDA's registration regulation. Further, FDA disagrees that the email address for the U.S. agent will not be useful for the Agency. We plan to use the email address information to assist us in routine and emergency communications with the U.S. agent. In addition, we plan to use the email address information to help us verify that the person identified as a U.S. agent in a facility's registration has agreed to serve in that role. As described elsewhere in this **Federal Register** document, after a foreign facility completes its registration or updates its U.S. agent information (including as part of registration renewal), FDA will verify that the person identified as the U.S. agent for the foreign facility has agreed to serve as the facility's U.S. agent (see §§ 1.231(a)(5) and (b)(7) and 1.234(c)(2) and (d)(5)). In addition, as described in section IX of this document, facilities must submit updates within 60 calendar days of any change to any of the registration information previously submitted, including information about the U.S. agent.

(Comment 42) Comments recommend that FDA create an exemption from the requirement that facilities provide an email address for the owner, operator, or agent in charge of a facility for facilities that do not have email addresses or Internet access. One comment requests that providing the email address of the owner, operator, or agent in charge be optional.

(Response 42) Although section 102(a)(1)(A) of FSMA requires submission of email address information for the contact person of domestic facilities and the U.S. agent of foreign facilities, often these persons are not the same as the owner, operator, or agent in charge of the facility. We are requiring email addresses for the owner, operator, or agent in charge of food facilities in § 1.232(a)(6) in order to facilitate quick communications with those individuals. Such communications may be necessary in the event of food-related emergencies and, where applicable, suspensions of a food facility's registration. However, we understand that there may be circumstances in which an owner, operator or agent in charge of a facility is not able to obtain an email address. We expect that these circumstances will the same or similar to the circumstances that may cause a facility to receive a waiver from the electronic registration requirement in accordance with § 1.245. To account for these circumstances, we are providing in final § 1.232(a)(6) that the email address be added to the information required regarding the owner, operator, or agent in charge of the facility, except when FDA has granted a waiver under § 1.245. Consequently, under final § 1.232(a)(6), a food facility registration must include the name, address, and phone number of the owner, operator or agent in charge. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted a waiver under § 1.245.

B. Requirement for a Unique Facility Identifier

(Comment 43) Comments state that FDA does not have express legal authority to require a D–U–N–S number. The comments state that Congress amended the registration requirements in section 415 of the FD&C Act as part of FSMA, and that Congress could have, but did not, require the submission of D–U–N–S numbers.

(Response 43) We have replaced the proposed requirement that registrations include a D–U–N–S number with a requirement that they include a UFI recognized as acceptable to FDA. We believe that we have adequate legal authority for this requirement in the final rule. As to the comments' statement that Congress could have, but chose not to, include a UFI requirement in FSMA, we do not believe that the lack of such a requirement in FSMA indicates that Congress did not authorize FDA to require such identifiers. As we stated in the proposed rule, the UFI requirement is grounded in the statutory objective of efficiently enforcing the food safety and other requirements of the FD&C Act. By requiring UFIs, FDA will be able to verify the facility-specific address information associated with those identifiers. Such verification should increase the accuracy of FDA's food facility registration database. As a consequence, FDA investigators will have access to more accurate food facility information, and will therefore be able to more efficiently identify and locate food facilities for inspection. As a result, FDA will be able to more efficiently conduct inspections under section 704 to enforce the food safety and other requirements of the FD&C Act.

FDA's decision to require UFIs in food facility registration is also consistent with FDA's mandate under section 415(a)(5) of the FD&C Act to compile and maintain an up-to-date list of registered food facilities, as well as the requirement in section 415(a)(2) of the FD&C Act that registrants submit information necessary to notify FDA of the name and address of each facility at which the registrant conducts business. Indeed, the verification that UFIs provide will help ensure that the food facility list is up-to-date and contains accurate information concerning the addresses of food facilities. Moreover, an up-to-date list that includes information necessary to notify FDA of the name and address of food facilities will aid FDA in efficiently responding to a terrorist threat or other food-related emergency. Finally, FDA's decision to require unique facility identifiers is consistent with the direction contained in section 305(d) of the Bioterrorism Act (Pub. L. 107–188, 116 Stat. 594, 668–69) to ensure adequate authentication protocols to enable identification of the registrant and validation of the registration data for registrations submitted to FDA electronically. Verifying information in connection with a UFI for a food facility will provide FDA with a protocol to enable FDA to identify food facilities and verify certain registration information for those facilities.

(Comment 44) Comments suggest obtaining a D–U–N–S number is a duplicative effort for facilities and would not provide assurance of the most up-to-date and accurate information for a facility considering that information in both databases is voluntarily entered by the facility. One comment states that use of an identification number such as a D–U–N–S number would not lead to increased accuracy because with both a D–U–N–S number and food facility registration, facilities self-report information. Comments urge FDA to allow multiple identifiers for facilities as opposed to solely relying on D–U–N–S. Some comments recommend FDA utilize the U.S. Customs and Border Protection's (CBP) identification number system and/or the Prior Notice (PN) system for foreign registration verification as opposed to a D–U–N–S number. Comments encourage FDA to allow facilities other options for a specific facility identifier that include using certifications and identifiers from State agencies. Comments state that programs for use of identifying traders are best dealt with at an international level by the World Customs Organization. This comment states that no one identification system is better than another and that FDA should not impose this particular system worldwide. One comment encourages FDA to work with State, local, and tribal agencies to develop a UFI without relying on a third-party system.

(Response 44) As stated previously in this **Federal Register** document, the final rule requires that registrations include UFIs, not D–U–N–S numbers. We believe that this change provides additional flexibility. We anticipate that we will issue guidance specifying which UFIs or identifiers FDA recognizes as acceptable, and we expect to recognize D–U–N–S numbers as acceptable identifiers.

We disagree with the comments stating that UFIs will be duplicative and will not assist FDA in obtaining up-to-date information about food facilities. We anticipate that UFIs will help ensure that the identified facility is, in fact, the food facility in the food facility registration submission. The D–U–N–S number system, for instance, is an internationally recognized unique number system that is updated on a regular basis. D–U–N–S numbers also provide for site-specific identification of business entities. Although business establishments may provide information about themselves to Dun and Bradstreet, Dun and Bradstreet does not rely on self-reported information alone. The company independently verifies certain information associated with establishments. The ability to verify the accuracy of this information will increase the accuracy of the registration database and, as a consequence, help provide FDA investigators with more accurate food facility information that they can use to more efficiently identify and locate food facilities for inspection. In addition, we expect that the UFI verification process will make it more difficult for unauthorized individuals to submit registrations on behalf of facilities because unauthorized individuals may not know a particular facility's UFI, or may be unable to provide an accurate facility-specific address.

To the extent that the comments are concerned about the burden of the requirement, we note that Dun and Bradstreet makes D–U–N–S numbers available at no cost. Further, as of mid-2013, approximately 70 percent of domestic facilities required to register with FDA and 64 percent of foreign facilities required to register with FDA, have D–U–N–S numbers (Ref. 9).

As to the comments suggesting we use CBP or PN systems, we do not agree that such identification systems would be appropriate. Not all food facilities import food, and therefore not all food facilities will necessarily have access to any CBP or PN system. Furthermore, we do not believe that any certifications and identifiers from State agencies would be adequate UFIs because any such certifications and identifiers would likely differ State by State, and States might not develop UFIs for foreign facilities. For these reasons, we do not agree that using the alternative identifiers suggested by the comments would allow FDA to accurately identify food facilities. Consequently, they would not allow FDA to efficiently enforce section 415 of the FD&C Act.

With respect to the comment stating that programs for use of identifying traders are best dealt with at an international level by the World Customs Organization and that FDA should not impose this particular system worldwide, FDA is responsible for administering the requirements of section 415 of the FD&C Act. Those requirements include the responsibility to maintain an accurate and up-to-date registration database. Our database needs are specific to the laws and regulations we implement, and we believe that we are in the best position to determine what UFIs should be acceptable. In addition, by requiring the submission of an acceptable UFI, we are not requiring worldwide adoption of any particular identification system. The requirement would only apply to food facilities that are required to register with FDA (*i.e.,* food facilities that manufacture/process, pack, or hold food for consumption in the United States).

Regarding the comment encouraging FDA to work with State, local, and tribal agencies to develop a UFI without relying on a third-party system, we may consider whether such an approach would be appropriate. However, we expect that undertaking the development of a new UFI system could entail significant resources.

(Comment 45) One comment states that a U.S. Government Accountability Office report stated that the U.S. General Services Administration has concerns regarding reliance on D–U–N–S numbers and has been looking into alternatives that would encourage competition (Ref. 10). The comment urges FDA not to require a D–U–N–S number for food facility registration.

(Response 45) As stated previously, the final rule does not require the submissions of D–U–N–S numbers; instead it requires the submission of UFIs recognized as acceptable to FDA. We will consider recognizing as acceptable UFIs other than D–U–N–S numbers.

(Comment 46) Comments state that the proposed requirement to obtain a D–U–N–S number would be burdensome and unfamiliar to many. Comments recommend FDA make the proposed D–U–N–S requirement optional for foreign facilities. They state that this would help alleviate the burden for foreign facilities because they state that it can take up to 2 weeks for foreign facilities to obtain D–U–N–S numbers. One comment states that facilities need time to implement the D–U–N–S number requirement, especially foreign facilities that may be unfamiliar with the process of obtaining a D–U–N–S number. The comment is also concerned that Dun and Bradstreet will be inundated with requests during the next biennial renewal period. In addition, comments state that it would be burdensome for facilities to maintain both food facility registration numbers and D–U–N–S numbers. One comment suggests that FDA should work with Dun and Bradstreet to make the iUpdate system available to facilities and make it clear to food facilities that they have access to the iUpdate system when obtaining a D–U–N–S number. One comment states that the Dun and Bradstreet Web site for obtaining D–U–N–S numbers is not reliable, and facilities may be prompted to request D–U–N–S number by telephone (at a large cost).

(Response 46) As stated in the previous paragraphs, we conclude that it is appropriate to require that food facilities, including foreign facilities, submit UFIs in their registrations. Use of a UFI, such as a D–U–N–S number, provides additional information than that provided by food facility registration numbers, because UFIs such as D–U–N–S numbers allow FDA to verify certain information submitted in registrations. Such verification is important for both domestic and foreign food facilities. As to the concern about the burden of this requirement, we do not agree that the process of applying for a UFI is unreasonably burdensome, including for foreign facilities. Nevertheless, in response to the comments, we are delaying the requirement to submit a UFI until the registration renewal period beginning October 1, 2020. We believe that this will provide adequate time for domestic and foreign facilities to obtain D–U–N–S numbers without cost and for facilities (both domestic and foreign) to become familiar with the process for obtaining D–U–N–S numbers. In addition, a D–U–N–S number can be acquired at any time, not only within the biennial registration renewal period. We do not anticipate that facilities will have difficulty obtaining UFIs as a result of the UFI provider being overburdened or its Web site being unreliable. But if such difficulties do arise, facilities should contact us so that we can look into the matter. Regarding the request in the comment that FDA work with Dun and Bradstreet to make the iUpdate system available to food facilities, we will look into the possibility and determine whether the system is appropriate for food facility registration.

(Comment 47) Comments state that the food facility registration number will serve as an adequate facility identifier. Comments state that there does not appear to be a problem with inaccurate data in the food facility registration database and state that requiring an additional identifier is therefore not necessary.

(Response 47) FDA will not discontinue the use of registration numbers. However, since FDA implemented the registration requirement in 2003, we have identified a number of accuracy-related problems in the registration database. One such problem involves incorrect facility address information. Accurate address information is critical to scheduling inspections efficiently, and without it FDA often faces the problem of "inspectional washouts," where an FDA investigator arrives for an unannounced inspection at a listed address only to find that the facility has gone out of business or is otherwise not located at the listed address. In fiscal year 2015, FDA experienced 629 inspectional washouts for foreign and domestic food facilities. We believe that requiring UFIs in registrations and verifying the facility-specific address associated with those numbers will help increase the accuracy of the address information contained in FDA's food facility registration database.

(Comment 48) Numerous comments state that it does not make sense for small businesses or hobbyists who operate out of their homes to obtain D–U–N–S numbers for the sole reason of registering with FDA.

(Response 48) Under § 1.227, a private residence is not a "facility." Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered. Accordingly, if the activities of small businesses or hobbyists who operate out of their homes meet customary expectations for a private residence, they would not have to register and therefore would not be required to obtain a UFI under this final rule. If, however, their activities do not meet customary expectations for a private residence, the small businesses or hobbyists would be required to register as food facilities and obtain a UFI. For the reasons outlined in the previous paragraphs, we believe that the process of applying for a UFI is reasonable and that it will not be unduly burdensome.

(Comment 49) Comments express concern over the confidentiality of D–U–N–S numbers. Comments state that FDA should confirm and clarify that D–U–N–S numbers as well as facility names, addresses, and other information submitted in registrations are not subject to public disclosures. One comment states that disclosure of D–U–N–S numbers could allow third parties to obtain the address of "pharmaceutical distribution warehouses" that also hold food, and that disclosure would allow criminals to identify large quantities of drugs. The comment also expresses concern about inadvertent disclosure of D–U–N–S numbers by FDA FOIA staff. Comments ask that FDA consult with the State Department and Foreign Governments "since mandating the collection of private data might run afoul of European privacy laws."

(Response 49) With respect to concerns about use of UFIs, including D–U–N–S numbers, leading to the disclosure of confidential information, we take appropriate measures to secure all data and records provided to the Agency, including data contained in food facility registrations. Furthermore, we note that under section 415(a)(5) of the FD&C Act, FDA's list of registered facilities and registration documents are not subject to disclosure under FOIA. In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person also is not subject to disclosure under FOIA. With respect to public disclosure, FDA intends to treat information about facilities' UFIs the same as it treats other information derived from registration submissions. It should also be noted that no registration information will be disclosed to a UFI provider, such as Dun and Bradstreet, as part of the verification process. Dun and Bradstreet could disclose the identity or location associated with a D–U–N–S number in some circumstances (such as for persons that pay for Dun and Bradstreet services), but any information that Dun and Bradstreet could disclose would not indicate whether a facility is registered or include any information provided to FDA as part of the registration process.

Regarding the concern expressed in one comment about the security of facilities that store both foods and drugs, it is unclear how the submission of a UFI for purposes of food facility registration places the facility at any additional risk. The food facility registration regulations do not require facilities to provide information about any products other than the food manufactured/processed, packed, or held by the food facilities, and, as previously stated, information derived from the registration list or registration documents are not subject to disclosure under FOIA if they would disclose the identity or location of a specific registered person.

With regard to concerns raised about foreign country privacy standards, we requested comment on the proposed requirements, and a wide range of entities had the chance to provide us feedback. We are not aware of information, nor did we receive information from comments, that a UFI requirement would violate a European Union privacy law. If an entity finds that a UFI requirement conflicts with specific local laws, they should contact FDA.

We also believe that finalizing a UFI requirement, as opposed to a D–U–N–S number requirement, will help foster potential competition with other UFI providers and encourage better customer service from providers recognized as acceptable to FDA.

(Comment 50) Comments request clarity regarding facilities that require a D–U–N–S number (*i.e.* headquarters and/or sub sites). Other comments encourage FDA to allow the use of the parent company's D–U–N–S number for separate facilities that a company may own so that companies that own multiple facilities need only use one D–U–N–S number. Comments also state that many companies' D–U–N–S numbers are typically handled by headquarters personnel who may be located at a different address than the facility itself.

(Response 50) Under the final rule, each facility must provide a UFI recognized as acceptable by FDA. Requiring identifiers that are unique to individual facilities is necessary to enable FDA to verify the facility-specific address information associated with those identifiers. Such verification will allow FDA to more efficiently identify and locate food facilities for inspection and to maintain an accurate and up-to-date registration database. Accordingly, FDA declines the suggestions to allow identifiers that are specific to parent companies instead of individual facilities.

(Comment 51) Comments ask if the requirement to supply a D–U–N–S number will apply to all facilities immediately, or if it will only apply to facilities not currently registered.

(Response 51) The requirement to provide a UFI will apply to all registrants, new and existing. For all registrants, as we stated previously in this document, we are delaying the compliance date for the requirement to submit a UFI recognized as acceptable to FDA until the registration renewal period beginning October 1, 2020. After a food facility provides a UFI, it will be required to update its registration with any changes to the identifier in accordance with § 1.234 of the final rule.

(Comment 52) Comments ask if facilities will have to provide a new D–U–N–S numbers if they change ownership.

(Response 52) If a facility comes under new ownership, the former owner must cancel the old registration in accordance with § 1.235 of the final rule, and the new owner must submit a new registration for the facility as specified in § 1.231 (see 21 CFR 1.234(b)). If a facility cancels its registration due to a change in ownership, the new owner, operator, or agent in charge must provide the appropriate UFI when registering the facility under new ownership.

(Comment 53) A comment states that FDA should prominently display on the registration Web site that a D–U–N–S number can be obtained at no cost and within a reasonable timeframe. In addition, the comment suggests that FDA provide a link on the FURLS Web page that facilities can use to contact FDA if they are asked to pay for a D–U–N–S number or to purchase additional D–U–N–S services, or if they cannot obtain a number within a reasonable time.

(Response 53) We will consider making changes to the registration Web site and the FURLS Web page to clarify which UFIs are recognized as acceptable to FDA and how to obtain a UFI. If facilities have difficulty obtaining a UFI, they are welcome to contact FDA at any time. We will consider providing further instructions regarding how to contact FDA on the FURLS Web page as well.

(Comment 54) One comment states that foreign facilities should be able to submit registrations without a D–U–N–S number, and then have 30 days to update the registration with the D–U–N–S number. The comment suggests that FDA conduct the verification step at that time. Furthermore, the comment recommends that FDA can maintain a log of instances involving registrations that were cancelled because a foreign facility did not have a D–U–N–S number and that FDA place those facilities on Import Alert. Furthermore, the comment suggests that in the 12 months prior to the next biennial registration period, FDA should add an optional D–U–N–S number field to Form FDA 3537.

(Response 54) We disagree that foreign facilities should have 30 days to update their registrations with a UFI. For all registrants, we are delaying the requirement to submit a UFI recognized as acceptable by FDA until the registration renewal period beginning October 1, 2020, and we believe that this delay will provide all facilities, including foreign facilities, with sufficient time to obtain a UFI recognized as acceptable by FDA. We also believe that it would be administratively difficult to implement the comment's suggestion that different registration information be submitted at different times. The Agency will consider adding an optional UFI field to allow facilities to voluntarily submit UFI information in advance of the October 1, 2020, date.

(Comment 55) Comments express concern over the availability of the D–U–N–S system to small facilities that do not have reliable access to the Internet.

(Response 55) Our understanding is that access to the Internet is not required for D–U–N–S numbers, and that a D–U–N–S number can be obtained by phone. If any food facilities have difficulty obtaining a UFI recognized as acceptable by FDA due to lack of access to the Internet or phone, they may contact FDA.

(Comment 56) Comments state that Dun and Bradstreet does not appear to account for additions or deletions to the Specially Designated Nationals (SDN) List. These comments suggest FDA establish an ongoing monitoring process that routinely verifies the food facility registration database against the current SDN list.

(Response 56) The U.S. Treasury Department's Office of Foreign Assets Control publishes a list of individuals and companies owned or controlled by, or acting for or on behalf of, targeted countries. It also lists individuals, groups, and entities, such as terrorists and narcotics traffickers designated under programs that are not country-specific. Collectively, such individuals and companies are called "Specially Designated Nationals" or "SDNs" (Ref. 11). The comment has not identified a compelling reason why we should establish an ongoing monitoring process that routinely verifies the facility registration database against the SDN list, and we decline to do so.

(Comment 57) Comments recommend FDA require that each facility's registration include its geographical coordinates instead of D–U–N–S numbers. Comments state that geographical coordinates are more easily accessible for each facility and are directly linked to a facility's physical location.

(Response 57) FDA declines to implement this recommendation. While geographical coordinates can provide longitude and latitude information about a facility, geographical coordinates may not always provide the same relevant and detailed information as a UFI. For instance, multiple, separate facilities may operate from a location with the same geographical coordinates, and geographical coordinate information may not reveal the complete address of a facility.

(Comment 58) Comments state that some individuals will have religious objections to the D–U–N–S number requirement because D–U–N–S numbers involve a mandatory universal numbering system.

(Response 58) If a registrant has religious beliefs that conflict with obtaining a UFI, they should contact FDA and explain why they are not able to comply with the requirement in the final rule.

C. Requirement To Include Food Product Categories

We proposed to amend § 1.232 to be consistent with FDA's October 2012 guidance document entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (Food Product Categories Guidance) (Ref. 5) and the FSMA amendments. Specifically, the proposed provision would require that a food facility registration include applicable food product categories of any food manufactured/processed, packed, or held at the facility, as identified on Form FDA 3537. We stated that we intend to address any further amendments of the food product categories contained on Form FDA 3537, if necessary and appropriate, through updates to the guidance document "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories."

(Comment 59) Comments state that it is confusing to update required food product categories by guidance since the guidance document is binding and, the comments say, looks indistinguishable from other guidance documents that are not binding. Comments recommend that the Food Product Category guidance document be called something other than "Guidance," such as "Binding Guidance," to set it apart. Comments encourage FDA to consider amending the food product categories through a mechanism other than guidance.

(Response 59) We disagree with these comments. Section 102 of FSMA amends section 415(a)(2) of the FD&C Act, to now provide, in relevant part, that, when determined necessary by FDA "through guidance," a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. We therefore believe it is appropriate to establish food product categories using guidance, and also to use the term "guidance" in describing the document. Because of Congress's explicit statutory authorization to effectuate a binding requirement based on findings in guidance, the Food Product Categories guidance document is not subject to the usual restrictions in FDA's GGP regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect (see 21 CFR 10.115(d) and (i)). Although we appreciate the comments' concern that this causes the Food Product Categories Guidance to differ from other guidance documents, we think that the guidance document itself makes this difference clear. In particular, we stated in the Food Product Categories guidance that we did not include the standard language regarding the "nonbinding effect of guidance" in the guidance because it is not an accurate description of the effect of the guidance (Ref. 5).

(Comment 60) Comments suggest that FDA should not require warehouses and storage facilities to identify food product categories that they handle because this information constantly changes. The comments state that it would therefore be burdensome for these facilities to be required to "constantly update" their food product category information.

(Response 60) Information about the categories of food a facility handles helps FDA conduct investigations and surveillance operations in response to food-related emergencies and to quickly alert facilities affected by such an incident if FDA receives information indicating the type of food affected. This is true for warehouse and storage facilities, as well as other facilities that manufacture/process, pack, or hold food. We therefore disagree with the suggestion to exempt warehouses and storage facilities from the requirement to include food product category information in their registrations. That said, it may not be necessary for warehouse facilities to "constantly update" their registrations. For warehouse facilities engaged in ongoing operations that frequently change food product categories, these facilities may select all of the food product categories that are normally part of their operations. If the warehouse has any updates to the food product categories that it handles, it is required to update its registration in accordance with § 1.234. The Agency will consider possible IT solutions to reduce the burden associated with selection of food product category information.

(Comment 61) Comments question whether FDA is proposing to remove animal feed product categories from Form FDA 3537 and, if not, request clarity on the definitions of each of the animal food product category listed on the form.

(Response 61) This final rule does not remove animal food product categories from Form FDA 3537, and registrants will continue to be required to provide information about food product categories for animal food. As to the comment's request for guidance on the meaning of the different food product categories for animal food, we do not agree that such guidance is necessary. We believe that many of the food product categories on Form FDA 3537 do not require elaboration. For instance, we believe that registrants understand the meaning of the term "pet food," which is one of the food product categories for animal food. To the extent that the comment seeks clarification on the categories that pertain to animal food ingredients, we believe that these categories are well understood in the animal food industry. For instance, every year the Association of American Feed Control Officials (AAFCO) issues the *Official Publication* (OP) that includes categories for various animal food ingredients, many of which overlap with the food product categories listed on Form FDA 3537 for animal food. In order to provide even greater consistency with the categories used by the animal food industry, FDA plans to update the Food Product Categories guidance to add several additional food product categories for animal food. Those categories are: Botanicals and herbs; direct fed microbials; forage products; and technical additives. In addition, we plan to revise the Food Product Categories Guidance to replace certain food product categories. Specifically, we plan to replace the "animal derived products" category with an "animal protein products" category, replace the "food processing byproducts" category with a "human food by-products not otherwise listed" category, and replace the "recycled animal waste products" category with a "processed animal waste products" category. We will update Form FDA 3537 to reflect changes that we make to the Food Product Categories guidance.

If facilities have specific questions about the food product categories for animal food, they may contact FDA.

(Comment 62) Comments propose utilizing FDA Product Codes instead of the food product categories currently on Form FDA 3537. Comments state FDA Product Codes "more specifically identify foods and thus allow FDA to more accurately assess risk," and note that FDA's draft guidance for industry on the voluntary qualified importer program (VQIP) recommends use of the product codes.

(Response 62) FDA's product code is a unique alpha-numeric code used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA. FDA requires submission of this data element for prior notice (21 CFR 1.281(a)(5)(i)), in part because the specificity provided by the FDA product code helps facilitate risk-based screening of imported products. The use of FDA product codes is also part of the application process for VQIP, as explained in the VQIP draft guidance (Ref. 12). At the same time, FDA requires the submission of food product category information for registration. Food product categories are for the most part more general and are tailored to food facility registration. FDA may use the food product categories in connection with product codes at the time of import. Specifically, FDA is able to use the information about food product categories to screen food imports because the Agency is able to match a registrant's food product category with the product code and common or usual market name submitted as part of prior notice. However, food product categories provide certain information that the product codes do not provide. For example, the fruit and vegetable categories include separate sub-categories for fresh-cut fruits and vegetables, raw agricultural commodities, and other fruit and vegetable products. Because fresh-cut fruit and vegetables present different risks from other fruits and vegetables, this information helps FDA target communications with facilities. The product codes do not distinguish fresh-cut from other fruit or vegetable products. For all of these reasons, we believe it is appropriate to continue to require food product categories for registration, and not FDA product codes. Further, we note that food facility registration and VQIP serve different purposes.

(Comment 63) One comment suggests that we modify Form FDA 3537 to allow facilities to write in the type of food that is being held at the facility in order to minimize the content of sections 10a and 10b on the form.

(Response 63) We decline the suggestion to modify sections 10a (general product categories for human consumption) and 10b (general product categories for animal consumption) to a blank column for the facility to write in a food category. We believe that it makes the registration process easier for facilities if there are designated food product categories from which they can choose. We also believe that the specific food product categories currently on Form FDA 3537 are necessary and appropriate for food facility registration, as indicated in the Food Product Categories Guidance.

(Comment 64) One comment agrees with the designation of "Bakery products, dough mixes, or icings [21 CFR 170.3(n)(1),(9)]" as a food product category, provided that the food product category is intended to encompass all of the foods covered by § 170.3(n)(1) and (9). The comment would alternatively support separate food product categories for the products covered by § 170.3(n)(1) and (9) if the different products covered by the two different provisions have unique risk profiles.

(Response 64) The food product category "Bakery products, dough mixes, or icings [21 CFR 170.3(n)(1),(9)]" is intended to encompass all of the foods covered by § 170.3(n)(1) and (9). If we make changes to the food product categories, we will update the Food Product Categories Guidance.

D. Requirement To Identify Activity Type

(Comment 65) Some comments state that requiring activity type information would be burdensome for facilities that hold many products (*i.e.*, warehouses) and perform various activities. Comments also state that this information is irrelevant to FDA's mission and operations, including inspection planning, determining inspection frequency, and responding to food-related emergencies. These comments suggest that activity type information should remain optional, as it is under the current food facility registration regulation. Other comments, however, state that they support the requirement that facilities provide activity type information. One comment states that the requirement will reduce the need for FDA to reach out to facilities to gather this same information. One comment suggests that FDA obtain activity type information in a written text field on the registration form instead of using a matrix similar to that currently used on Form FDA 3537, which matches activity type information with food product category information. The comment is concerned that warehouses that hold a number of different foods would be required to make frequent updates.

(Response 65) We disagree with the comments suggesting that we not require activity type information. As stated in the proposed rule (80 FR 19160 at 19173), information about activity type will provide FDA with important information regarding a facility's role in the U.S. food supply system, allowing us to better assess the facility's potential impact in cases of bioterrorist incidents or other food-related emergencies. Improved information about activity types will also allow us to better prepare investigators for inspections and assign appropriate investigators, and allow FDA to communicate more quickly and efficiently on various non-emergency issues, such as new regulatory requirements or policies. In addition, the activity type information will aid FDA in implementing section 421 of the FD&C Act, which requires FDA to identify high-risk facilities and mandates more frequent inspections for domestic high-risk facilities than for domestic non-high-risk facilities. Section 421(a)(1) of the FD&C Act sets forth the factors for FDA to use in identifying high-risk facilities, which include "[a]ny . . . criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources" (see section 421(a)(1)(F) of the FD&C Act). Among the criteria we have deemed necessary and appropriate for this purpose are type of activity conducted at the facility (manufacturer/processor, packer/repacker, etc.). Because the risk-based inspection mandate in section 421of the FD&C Act applies to facilities registered under section 415, and because we have identified information about the type of activity conducted at a facility as an important factor to consider when identifying high-risk facilities under section 421 of the FD&C Act, the activity type information will allow us to more efficiently enforce section 421. Therefore, we decline the recommendation to keep the activity types as optional data elements. We will consider IT and formatting solutions that will make it less burdensome to provide this information, such as drop down menus or "Select all" options. Regarding the request that FDA obtain activity type information through a written text field, we decline that request. We do not believe that using written text fields would easily enable facilities to match the activity type information with the food product category information. Also, the comment does not explain why written text fields would be less burdensome than the matrix used on current Form FDA 3537, which allows facilities to check boxes indicating applicable activity types. (Currently, the activity type information on Form FDA 3537 is optional.)

(Comment 66) One comment asks whether foreign facilities must provide activity type information about all foods associated with the facility, or only about foods exported for consumption in the United States.

(Response 66) Facilities are only required to provide activity type information about food that the facility manufactures/processes, packs, or holds for consumption in the United States. FDA is requiring information about activity types to help FDA better assess the facility's potential impact in cases of bioterrorist incidents or other food-related emergencies, and to help the Agency identify facilities with which to communicate on various issues, among the other reasons discussed in the previous paragraphs. We anticipate that we will only need to assess facilities and communicate with facilities with respect to foods that are consumed in the United States.

(Comment 67) A comment suggests that FDA provide definitions for the following activity types: Ambient human food storage warehouse/holding facility; refrigerated human food warehouse/holding facility; and frozen human food warehouse/holding facility.

(Response 67) In the proposed rule, we provided tentative definitions for the activity types required in § 1.232 (80 FR 19160 at 19173 to 19174) and we requested comment on whether to define the specified activity types. We conclude that it is not necessary to provide definitions in the regulatory text, considering that we provided tentative definitions in the proposed rule and that we understand the activity type terms to be generally well-understood by industry. If additional clarification is needed, we will consider providing guidance on the activity type definitions, as appropriate. We believe that any such clarification will be better provided in a guidance document that follows our GGP regulations in 21 CFR

10.115 because we will be better able to provide clarification quickly as the need may arise.

(Comment 68) One comment recommends that FDA divide the "ambient human food warehouse/holding facility," "refrigerated human food warehouse/holding facility", and "frozen human food warehouse/holding facility" activity types into two sub-categories: "Ambient human food warehouse/holding facility", and "refrigerated/frozen human food warehouse/holding facility." The comment states that three sub-categories are not useful and may lead to confusion.

(Response 68) We disagree with this comment. Information distinguishing whether a facility is engaged in refrigerated or frozen warehousing/holding is important to the Agency when responding to food-related emergencies. Generally speaking, the closer a refrigerated or frozen food gets to ambient temperature, the more potential there is for spoilage and foodborne illness to occur. Refrigerated foods have a more narrow window before they reach a temperature where spoilage occurs. Facilities that warehouse such foods would therefore be of most concern to FDA in an emergency involving power outages. For example, during a response to a natural disaster in which power outages occur, the Agency might choose to first focus on refrigerated warehouses to ensure proper handling of foods that are at risk of spoilage and foodborne illness.

(Comment 69) A comment requests that FDA provide clarification regarding the "farm mixed-type facility" activity type. Specifically, the comment asks FDA to confirm whether it is acceptable for a farm that packs fresh produce from other farms to register as a "farm mixed-type facility." The comment also asks FDA to confirm that a farm that packs its own produce should not register.

(Response 69) In § 1.227 of our regulations, we define a mixed-type facility as an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the "farm" definition that require the establishment to be registered. FDA added the definition in § 1.227 for mixed-type facilities in the final rule for "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food." Also in that rulemaking, we revised the "farm" definition in § 1.227 so that it no longer limits establishments that fall within the "farm" definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised "farm" definition in § 1.227, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the "farm" definition if it packs and holds RACs grown on that farm or another farm under the same ownership, and also if it packs and holds RACs grown on another farm. Any such establishment that meets the "farm" definition is not subject to the requirement to register under section 415 and therefore is not required to provide FDA with activity type information in accordance with this final rule. However, if the farm engages in other activities that require the establishment to be registered, it is required to provide FDA with activity type information in accordance with § 1.232(a)(8) and select farm mixed-type facility.

(Comment 70) One comment asks FDA to clarify what it means by farm mixed-type facility as a facility type and to develop a plan for on-farm inspections and to train investigators on conducting such inspections. Furthermore, the comment requests that FDA develop outreach and education plans to help farms understand the registration process, in particular farms that have to register because they are mixed-type facilities.

(Response 70) In § 1.227 of our regulations, we explain that a mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. We will consider appropriate ways to train and prepare investigators for inspections of mixed-type facilities. As to the request that FDA provide education and outreach to help farms understand the registration process, we agree with comments that stress the importance of education and outreach. Within the Agency, we are establishing a Food Safety Technical Assistance Network and we plan to provide updated guidance concerning the registration requirements.

(Comment 71) Comments encourage FDA to allow the activity type for facilities that warehouse/hold food to indicate that their storage facilities are solely engaged in the storage of packaged food not exposed to the environment. The comment states that this information will assist FDA in setting inspection priorities and conducting inspections at storage facilities. The comment states that such facilities pose a very limited, if any, food-safety risk. The comment also mentions that a citizen petition submitted for FDA review requests an exemption from certain FSMA requirements for storage facilities that are solely engaged in the storage of packaged food not exposed to the environment.

(Response 71) FDA declines this suggestion. We agree that different food safety requirements should apply to facilities solely engaged in the storage of unexposed packaged food, and in the final rule for preventive controls for human food we have exempted such facilities from 21 CFR part 117, subparts C (hazard analysis and risk-based preventive controls) and G (supply-chain program), and provided for modified requirements if the food requires time/temperature control for safety. However, for purposes of food facility registration, we do not agree that it is necessary for facilities to separately identify whether they are solely engaged in the storage of packaged food not exposed to the environment. In the final rule, we are dividing the (previously optional) activity type of "warehouse/holding facility" for facilities that hold food for human consumption into three sub-categories. Those three sub-categories are "ambient human food temperature warehouse/holding facility," "refrigerated human food warehouse/holding facility," and "frozen human food warehouse/holding facility." We anticipate that the information that we will gather from these sub-categories will be sufficient to allow us to more efficiently respond to food-related emergencies. For example, if FDA receives information indicating that refrigerated or frozen warehouses/holding facilities could be affected by power outages, FDA would be able to communicate with such facilities about the incident. We do not anticipate that information about whether a facility is solely engaged in the storage of unexposed packaged food will be of much additional utility in responding to an emergency food incident.

Regarding the citizen petition submitted to FDA (Docket No. FDA 2011–P–0561–CP), the Agency will respond to the citizen petition in accordance with 21 CFR part 10.

(Comment 72) A comment encourages FDA to leave sections 8 and 9 on form FDA 3537. The comment states that these sections contain important information about food facilities.

(Response 72) We do not plan to remove sections 8 ("Seasonal facility date") from Form FDA 3537. In that section, we provide an optional field for facilities to give the approximate dates that they are open for business, if their operations are on a seasonal basis. We plan to retain seasonal facility dates as an optional field. Section 1.233 of the final rule provides that FDA encourages, but does not require, registrants to submit items that are indicated as optional on Form FDA 3537.

Regarding section 9 ("Types of storage") on Form FDA 3537, we are removing this section from the form. In that section, which is for facilities that are primarily holders, we make it optional for facilities to identify whether the facility's type of storage is ambient storage, refrigerated storage, or frozen storage. Because facilities are now required to provide this information as part of the activity type requirement in § 1.232(a)(8) of the final rule, it would be duplicative to provide facilities with the option of completing this information in a separate section of the registration form.

(Comment 73) Comments recommend that LACF and acidified food processing be treated as an activity type, not a food product category. Comments state that there are many foods that are LACF or acidified foods that also fall within other food product categories (such as baby food, cheese, and salad dressings). Comments state that FDA investigators would be able to better prepare for inspections if facilities select the activity type "low-acid and acidified food processing" in conjunction with the applicable food product category (*e.g.*, cheese) for the food produced at the facility.

(Response 73) We agree with these comments. The final rule includes acidified food and low-acid food processing in the list of activity type options. In addition, we will update the Food Product Categories Guidance to remove acidified foods and LACF as food product categories. We also plan to update the Food Product Categories Guidance to list molluscan shellfish as a food product category. Previously, Form FDA 3537 included "molluscan shellfish establishment" as an optional activity type. However, the list of activity types in this final rule does not include molluscan shellfish establishments. We are revising Form FDA 3537 to reflect these changes.

E. Requirement To Provide Assurance That FDA Will Be Permitted To Inspect

(Comment 74) One comment disagrees with the requirement that facilities provide assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. The comment states that this requirement violates a country's sovereignty and that facilities are subject to the national laws of the country in which they are located, and should therefore not be required to agree to inspection by FDA without the permission of their country's government.

(Response 74) Section 415(a)(2) of the FD&C Act, as amended by section 102(b) of FSMA, requires that food facility registrations contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. We do not agree that requiring this assurance violates the sovereignty of countries in which foreign facilities are located. The assurance is required for food facilities in order to complete their food facility registration. The assurance does not require foreign facilities to disregard the laws of the countries in which they are located, nor does it require the foreign countries to relinquish any sovereignty. When FDA selects foreign food facilities for inspection that have registered with FDA because they manufacture/process, pack, or hold food for consumption in the United States, FDA involves the foreign governments by generally sending an advance notification to the Competent Authority responsible for food safety in the country where FDA will be conducting an inspection. Under the FSMA amendments to the FD&C Act, FDA has the authority to take action if the Agency encounters inspection refusals. Specifically, FDA may refuse admission of food into the United States when that food is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, that refuses to allow inspection (see section 807(b) of the FD&C Act).

VIII. Comments on Proposed § 1.233—Are There Optional Items Included in the Registration Form?

We proposed to amend § 1.233 to provide that FDA encourages, but does not require, registrants to submit items that are indicated as optional on the Form FDA 3537. We proposed for this amendment to remove the optional items currently listed § 1.233. We are finalizing this amendment as proposed, for two reasons. First, the final rule converts several of the optional items in current § 1.233 into required items in revised § 1.232. Second, we believe FDA recommendations for optional items to include in food facility registrations are better addressed in guidance documents that follow our GGP regulations in 21 CFR 10.115.

IX. Comments on Proposed Amendments to § 1.234—How and When Do You Update Your Facility's Registration Information?

We proposed to amend § 1.234(a) to shorten the time period for a food facility to update its registration from 60 to 30 calendar days. We also proposed to amend § 1.234(b) to provide that when the reason for the update is a change in owner, the former owner must cancel the registration in 30 calendar days instead of the 60 calendar days allotted in current § 1.234(b). As discussed in the paragraphs that follow, we are not finalizing these proposals.

In addition, we proposed to amend § 1.234(a) to require that for updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the owner, operator, or agent in charge who authorized submission of the update. We are finalizing this requirement in the final rule, with modifications. Final § 1.234(a) provides that for updates not submitted by the owner, operator, or agent in charge, the update must include the email address of the individual who authorized the update, unless FDA has granted a waiver under § 1.245. We are allowing for a waiver for the same reasons as those discussed in Response 44.

Further, we proposed to amend § 1.234(d) to provide that beginning January 4, 2016, electronic updates will be mandatory unless a waiver under § 1.245 has been granted. For the reasons discussed in section VI.A of this document, final § 1.234(d) delays the requirement for electronic submission of cancellations. Specifically, final § 1.234(d) provides that updates must be submitted electronically beginning January 4, 2020. Final § 1.234(d) also provides that if FDA has granted a waiver under § 1.245, cancellations may be made by mail or fax.

(Comment 75) Comments oppose shortening the time period for registration updates. Comments state that FDA did not provide any examples of when a shortened time period for updates would have better enabled FDA to schedule inspections or more effectively respond to food safety issues. Comments state that a shortened time period would increase the regulatory burden on food facilities. One comment encourages FDA to consider the difference in public holidays as well as time and language differences between the United States and foreign countries. The comment states that facilities in foreign countries may need a longer amount of time to update the information and suggests keeping 60 calendar days for submitting updates. Some comments state that, given the potential for criminal penalties for committing prohibited acts under the FD&C Act, the shortened time period does not provide a reasonable amount of time for compliance, particularly for businesses that are in the midst of reorganizations.

(Response 75) In response to these comments, we are not shortening the time period for the submission of updates in § 1.234(a). Consequently, we will continue to allow owners, operators, or agents in charge of a facility 60 calendar days to submit updates to any changes of the required registration elements previously submitted. We believe that this strikes an appropriate balance between the concerns expressed in the comments and FDA's need to maintain an accurate and up-to-date registration database. In addition, we are not shortening the time period in § 1.234(b). Consequently, when the reason for the update is a change in owner, the former owner will continue to have 60 calendar days to cancel the registration, as is currently provided in current § 1.234(b).

X. Comments on Proposed Amendments To § 1.235—How and When Do You Cancel Your Facility's Registration Information?

We proposed to amend § 1.235 to shorten the time period for cancelling registrations from 60 calendar days to 30 calendar days. Specifically, proposed § 1.235(a) would replace a 60-calendar-day requirement with a 30-calendar-day requirement, providing that facilities cancel their registrations within 30 calendar days of the reason for cancellation (*e.g.,* facility ceases operations, ceases providing food for consumption in the United States, or is sold to a new owner) instead of the 60 calendar days in current § 1.235(a). As discussed in the following paragraphs, we are not finalizing this proposal.

In addition, we proposed to amend § 1.235 to require in § 1.235(d) that beginning January 4, 2016, owners, operators, or agents in charge must cancel their registrations electronically, unless a waiver under § 1.245 has been granted. For the reasons discussed in section VI.A of this document, final § 1.235(d) delays the requirement for electronic submission of cancellations. Specifically, final § 1.235(d) provides that cancellations must be submitted electronically beginning January 4, 2020. Final § 1.235(d) also provides that if FDA has granted a waiver under § 1.245, cancellations may be made by mail or fax. Also in the proposed rule, we proposed to amend § 1.235(b)(5) to require that for cancellations not submitted by the owner, operator, or agent in charge of the facility, the cancellation must include the email address of the owner, operator, or agent in charge who authorized the cancellation. We are finalizing this requirement in the final rule, with modifications. Final § 1.235(b)(5) provides that cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the cancellation, unless FDA has granted a waiver under § 1.245 of the final rule. We are allowing for waivers for the same reasons discussed in Response 44.

In addition, we are deleting proposed § 1.235(d)(7) of the final rule, because it is not applicable for cancellations. Furthermore, we have redesignated proposed § 1.235(d)(8) to § 1.235(d)(7) in the final rule and are making edits to clarify the process FDA will use to confirm cancellations submitted through mail or fax. We state in § 1.235(d)(7) of the final rule that the registration will be considered cancelled once FDA enters the facility's cancellation data into the registration system. FDA will send the registrant a cancellation confirmation.

(Comment 76) Comments disagree with FDA's proposal to shorten the time period for cancellations from 60 calendar days to 30 calendar days. Comments state that reducing the time period for cancellations would be burdensome without providing any commensurate benefit to public health. Additionally, some comments suggest that the time period should be increased, not decreased, to 90 days.

(Response 76) In response to these comments, we are not shortening the time period for the submission of cancellations in § 1.235(a) of the final rule. Consequently, owners, operators, and agents in charge will continue to be required to cancel registrations within 60 calendar days of the reason for cancellation. Just as with our decision to not shorten the time period for the submission of updates in § 1.234(a) of the final rule, we believe that this strikes an appropriate balance between the concerns expressed in the comments and FDA's need to maintain an accurate and up-to-date registration database. We do not believe that lengthening the time period for submitting cancellations would strike an appropriate balance. Current § 1.235 provides 60 calendar days to cancel, and we are not aware of any specific instances in which facilities have found this time period to cause difficulties.

XI. Comments on Proposed Amendments to § 1.241—What Are the Consequences of Failing To Register, Update, Renew, or Cancel Your Registration?

Proposed § 1.241(c) proposed to amend the registration regulation to provide that FDA may cancel registrations in certain additional circumstances in addition to those currently specified in current § 1.241. Specifically, we proposed to amend § 1.241(c) to provide that FDA will cancel a registration if FDA independently verifies that the facility is not required to register, if information about the facility's address was not updated in a timely manner in accordance with § 1.234(a), or if the registration was submitted to FDA by a person not authorized to submit the registration under § 1.225. In addition, proposed § 1.241(c) proposed to further amend the registration regulation by also providing that FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew the registration in accordance with § 1.230(b). Similarly, we proposed to add § 1.241(b) to the registration regulation to specify that FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b), and FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act.

FDA proposed to cancel registrations in these additional circumstances based on our experiences with invalid registrations during the approximately 10 years we have spent administering food facility registration, as well as to improve the accuracy and utility of the food facility registration database such that FDA would be able to maintain a more up-to-date list of registered facilities in accordance with section 415(a)(5) of the FD&C Act. A more accurate and up-to-date list will enable investigators to more efficiently locate food facilities for inspection and will better enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency. In addition, our proposal to cancel registrations when a facility has failed to renew its registration in accordance with § 1.230(b) was designed to respond to the FSMA amendments. FSMA amended section 415 of the FD&C Act to require food facilities that are required to register with FDA to renew their registrations with FDA every other year. Cancelling the registrations of facilities that have failed to do so will allow FDA to efficiently enforce the renewal requirement. It will also allow FDA to efficiently implement its obligation under section 415(a)(5) of the FD&C Act to maintain an up-to-date list of facilities. The proposal is also consistent with the requirement in section 415(a)(2) of the FD&C Act that facilities notify FDA in a "timely manner" as to changes in their registration information, including their address information. We are finalizing the amendments to § 1.241 as proposed, with one modification. We are revising § 1.241(c) of the final rule to state that if we cancel a facility's registration, we will send a confirmation of the cancellation using contact information submitted by the facility in the registration database. We are making these edits to clarify the process FDA will use to confirm cancellations in these additional circumstances.

(Comment 77) Comments request that the final rule include safeguards for when inadvertent technical mistake are the basis for cancellation, such as a period of time during which facilities may make corrections or a response process initiated by FDA. Comments also state the final regulations should specifically state that FDA will send notice to facilities facing potential cancellations indicating the Agency's intent to cancel the registration and the basis for the cancellation. Comments state that wrongful cancellations could cause significant hardship. Some comments also state that facilities should have 60 days to take corrective action before FDA cancels a registration. Some comments state that registrants should have due process prior to FDA cancelling a registration.

(Response 77) Our amendments to § 1.241(c) will maintain the requirement in current § 1.241(b) that FDA will cancel registrations if the Agency "independently verifies" that the specified circumstances are satisfied. In the proposed rule, we stated that we anticipate that in many cases it would be appropriate for FDA to send notices to facilities facing potential cancellation indicating our intent to cancel their registrations and the basis for such cancellations. We also stated that we anticipated that, when appropriate, if the circumstances meriting possible cancellation are corrected within 30 days after notice is provided, we would not cancel the registration. We further stated that we anticipate that if facilities do not respond within 30 days, or if corrective action is otherwise not taken within that time period, we would determine that we conducted an independent verification and would then cancel the registration. If a facility believes its registration was cancelled in error, the facility would be able to contact FDA. We also stated in the proposed rule that we anticipated that it would not be appropriate to provide the 30-day window for corrective action if the basis for cancellation is an expired registration due to failure to renew a registration in accordance with § 1.230(b). In those circumstances, a facility would have already received notice of its obligation to renew (80 FR 19160 at 19177). FDA understands the serious nature of cancelling a registration, and we plan to provide appropriate notice to facilities facing cancellation consistent with our statements in the proposed rule. However, we decline the request to amend the regulatory text to specify the specific notice we will provide. The facts in each scenario involving a potential cancellation are likely to be unique, and we do not think it would be appropriate to follow a single procedure for each cancellation. In addition, we decline to commit to providing registrants 60 days after notice is provided before cancelling registrations. We believe that 30 days will generally provide registrants with sufficient time to respond to any questions or concerns raised by FDA and take corrective action if appropriate. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration. We believe that this approach will provide adequate due process to facilities.

(Comment 78) Other comments urge FDA to provide a 30-day notice before a registration is considered expired, to ensure due process, and to allow facilities to respond. The comments state that facilities should have the opportunity to allow potential gaps in communication or misunderstandings to be resolved.

(Response 78) We do not agree that it is necessary to provide a 30-day notice before a registration is considered expired. Leading up to and throughout the registration renewal period, we plan to notify registrants of their obligation to renew their registrations and the deadline for doing so. We also plan to notify registrants that failure to renew their registrations in accordance with § 1.230(b) will cause FDA to consider the registrations expired. Additionally, we plan to notify registrants that we will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act. Because facilities will already receive notice of their obligation to renew throughout this process, we do not agree that it is necessary to provide an additional 30-day notice before cancelling registrations that expired because the facility has failed to renew its registration in accordance with § 1.230(b).

(Comment 79) Comments recommend that FDA provide similar procedures when cancelling a registration to those that the Agency provides when suspending a facility's registration, such as providing an opportunity for a hearing and an opportunity to reinstate the registration.

(Response 79) We disagree. As specified in section 415(b)(2) regarding registration suspensions, FDA will provide a registrant subject to a suspension order with an opportunity for an informal hearing on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. Suspensions involve a factual determination by FDA that there is a reasonable probability of serious adverse health consequences or death. See section 415(b)(1) of the FD&C Act (providing that the Secretary may suspend a facility's registration if the Secretary determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals). We do not believe that the same procedures used for registration suspensions are necessary for registration cancellations because registration cancellations are unlikely to present the kind of factual issues involved in registration suspensions.

Registration cancellations under § 1.241 do not involve determinations made by FDA regarding the probability of food safety hazards. They are instead based on a facility's failure to itself comply with certain requirements for food facility registration. Those requirements are administrative in nature. Further, we believe that the procedures in § 1.241 are adequate to ensure fairness. FDA will cancel registrations if it independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) of the final rule or the registration was submitted by a person not authorized to submit the registration under § 1.225. FDA will not cancel registrations in these circumstances if it does not independently verify the relevant facts. In addition, for registrations that FDA cancels as a result of the facility's failure to renew the registration, the facility will have received multiple notices from FDA reminding it of the registration renewal requirement. If we nevertheless cancel a registration in error, facilities should contact FDA so that we can look into the matter.

(Comment 80) Comments recommend that FDA annually review imports to determine whether registered foreign facilities have imported food into the United States during the preceding year and cancelling registrations for facilities that have not done so.

(Response 80) We decline to conduct such a review of registrations. The comment does not explain why such a use of FDA resources would be warranted, especially in light of the effect that the biennial registration renewal requirement has helped to routinely remove inactive registrations.

(Comment 81) One comment states that criminal and civil liability for lack of compliance with the registration requirements would be a disproportionate response from FDA. The comment states that the possibility of such liability may "result in a lack of willingness by U.S.-based agents to take responsibility" for foreign entities.

(Response 81) Under section 415 of the FD&C Act, owners, operators, and agents in charge of facilities are required to register with FDA. In addition, under section 301(dd) of the FD&C Act, the failure to register in accordance with section 415 is a prohibited act. Further, the causing of a prohibited act and being responsible for the commission of a prohibited act are subject to civil and criminal sanction under the FD&C Act (see sections 301, 302 (21 U.S.C. 332), and 303 (21 U.S.C. 333) of the FD&C Act). We believe that it is consistent with the FD&C Act for the registration regulation to specify in § 1.241 that the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act and a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Indeed, the registration regulation has specified this since 2003. To the extent that the comment is concerned about liability for a foreign facility's violations of requirements under section 415 of the FD&C Act, FDA's practice is to take enforcement action based on the facts of the case and the seriousness of the violations.

(Comment 82) Comments state that some establishments, such as farms, have registered with FDA even though they are not required to. The comments state that FDA should not cancel the registrations for such establishments. In addition, some comments urge FDA to allow entities to register that are not required to register, stating that FDA may find it useful to have information about such entities.

(Response 82) We disagree. Not all food-related establishments are required to register under section 415 of the FD&C Act. Only food facilities not exempt under § 1.266 are required to register, and farms are not food facilities. See section 415(c)(1) (providing that the term "facility" does not include farms); 21 CFR 1.226 (establishing that the registration requirements in 21 CFR part 1, subpart H, do not apply to farms); 21 CFR 1.227 (establishing separate definitions for "facility" and "farm"). FDA uses registration information to identity facilities for inspection and for communications on both routine and emergency matters. A registration database that includes establishments registered as food facilities but that are not, in fact, food facilities hinders these efforts, compromising FDA's ability to strategically target inspections and communications. We therefore believe it is appropriate for FDA to cancel the registrations for such establishments. In addition, we do not believe that the comment has identified reasons why it would be useful to have entities participate in food facility registration under section 415 of the FD&C Act that are not required to register under section 415.

(Comment 83) A comment recommends that FDA conduct broad education and outreach regarding registration requirements, before seeking civil or criminal penalties on entities that are newly subject to registration requirements, and that therefore may be unfamiliar with the requirements.

(Response 83) We recognize that there will be questions about registration requirements. We agree that education and outreach are important, and we plan to develop additional education and outreach strategies as appropriate. In addition, we are establishing a Food Safety Technical Assistance Network to allow us to respond in a timely and consistent way to industry questions.

(Comment 84) Some comments urge FDA not to dispose of registration information from cancelled registrations, stating that keeping this additional information on file could prove useful to FDA.

(Response 84) FDA will archive information from inactive food facility registrations as appropriate.

XII. Comments on Proposed Addition of § 1.245—Waiver Request

In the proposed rule, we proposed for § 1.245 to provide that to request a waiver from the requirement to submit registrations and registration renewals electronically, a registrant must submit a written request to FDA that explains why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. In the proposed rule, FDA tentatively concluded that reasons for why it may not be reasonable for a registrant to submit a registration or registration renewal to FDA electronically may include conflicting religious beliefs or where a registrant does not have reasonable access to the Internet (80 FR 19160 at 19177 to 19178).

In the final rule, we are finalizing the option of a waiver. However, we are revising § 1.245 of the final rule to clarify that FDA must have already granted the waiver in order for the electronic submission requirement to not apply. We believe that this requirement was implicit in proposed § 1.245, but we have revised the regulatory text to avoid any possible confusion. We are also revising § 1.245 of the final rule to provide that a waiver is available not only from the requirement to submit registrations and registration renewals (which also includes abbreviated renewals) electronically, but also from the requirement to submit updates and cancellations electronically. In addition, we are also expanding the waiver option so that waivers are also available from the requirement in § 1.232(a)(6) to provide the email address of the owner, operator, or agent in charge of the facility, and also from the requirement in §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5) to provide the email address for the individual who authorized submission of a registration renewal, registration, update, or cancellation, respectively, when such submissions are not made by the owner, operator, or agent in charge of the facility. Finally, we are revising proposed § 1.245 to no longer refer to January 4, 2016, as the date on which electronic registration submissions will begin to be required. Instead of January 4, 2016, we now refer to January 4, 2020. Accordingly, final § 1.245 provides that under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d), beginning January 4, 2020, the owner, operator, or agent in charge must submit registrations, registration renewals, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement. Section 1.245 of the final rule also provides that under § 1.232(a)(6), the registration must include the email address of the owner, operator, or agent in charge of the facility, unless FDA has granted a waiver from such requirement. In addition, § 1.245 provides that under §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. Section 1.245 of the final rule further provides that to request a waiver from these requirements, the registrant must submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility.

(Comment 85) Comments support the proposed waiver provision, but some comments request that we clarify the grounds for granting waivers from the electronic registration requirement. Some comments request that FDA consider reasons for why a registrant would request a waiver from electronic submission of food facility registration in addition to those discussed in the proposed rule. Comments state that conflicting religious beliefs are not necessarily the only beliefs that lead an individual or entity to decide not to use technology. Comments state that there may be other reasons, such as philosophical or political reasons. Other comments state that the regulatory text should specifically recognize religious objections and lack of reasonable access to the Internet as reasons to grant a waiver from the electronic registration requirement.

(Response 85) We do not believe it is necessary to provide examples in the regulatory text for when FDA would grant a waiver because we believe that each waiver request should provide an explanation as to why it is not reasonable for the particular facility to submit a registration or registration renewal electronically to FDA, and we intend to consider each waiver request on a case-by-case basis. FDA stated in the proposed rule that reasons for why it may not be reasonable for a registrant to submit a registration or registration renewal to FDA electronically may include conflicting religious beliefs or where a registrant does not have reasonable access to the Internet. However, we do not intend to limit waivers only to those facilities that identify a religious reason for seeking a waiver or that point to lack of access to the Internet.

We will consider whether it would be helpful to provide additional guidance on the process for requesting waivers under § 1.245 of the final rule.

(Comment 86) Comments request that registrants not be required to submit additional waiver requests after a request has already been granted.

(Response 86) We agree that if a waiver has been requested and granted, the facility should not be required to submit future waiver requests each time the facility submits a renewal or updates the facility's registration information. Accordingly, once FDA grants a waiver, we will consider the waiver to be in effect for as long as the reasons for the waiver remain unchanged and the registration has not been cancelled.

XIII. U.S. Agent Voluntary Identification System

We requested comment on whether to issue a future guidance document to provide for the establishment of a U.S. Agent Voluntary Identification System (VIS or the system), or to otherwise create such a system. As envisioned, the system would be designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. Specifically, the system would allow a U.S. agent to directly provide FDA with the agent's contact information (that is, the same contact information required for foreign food facility registration) and the name of the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. agent contact information through foreign food facility registrations, many of which are submitted and updated by the facility, rather than the U.S. agent for the facility. The new system would allow agents to provide information about themselves, including their name, mailing address, phone number, email address, and emergency contact phone number, as well as the name of the facility or facilities for which the agent agrees to serve. After a U.S. agent has provided such information to FDA through the system, the Agency would provide the U.S. agent with an identification number. The U.S. agent could then provide the identification number to foreign facilities that the U.S. agent agrees to represent as a U.S. agent.

We sought comments on the creation of this voluntary system and whether it is likely to increase the accuracy of U.S. agent contact information and reduce the number of unauthorized and/or fraudulent U.S. agent listings.

(Comment 87) Numerous comments state the creation of a VIS would be beneficial.

(Response 87) We agree, and we plan to implement a voluntary U.S. agent identification system as described in the proposed rule. As we stated in the proposed rule, we will follow our GGP regulations in 21 CFR 10.115 when we implement this system (80 FR 19160 at 19179).

(Comment 88) Comments request that the system provide a mechanism for electronic resignation by the U.S. agent, as well as notice of changes to the foreign facility's registration, including when the registration is cancelled.

(Response 88) Under § 1.234(a) of the final rule, the owner, operator, or agent in charge of a facility may authorize an individual to update a facility's registration. The authorized individual may be, but is not required to be, the U.S. agent for the facility. If the authorized individual is the U.S. agent for the facility, the U.S. agent may update the information in the registration about who serves in that role. In addition, FDA plans to allow U.S. agents to electronically notify FDA that they no longer serve as the U.S. agent for a foreign facility. We also anticipate that the system will notify the U.S. agent if the registration for the foreign facility is cancelled. We plan to provide further information and details about the system in a future guidance document.

XIV. Editorial Changes and Other Changes

A. Editorial Changes

Proposed § 1.231 would provide that beginning January 4, 2016, electronic registration will be mandatory, including registration renewals, unless a waiver has been granted for the registrant. Proposed § 1.231 would also provide that beginning on January 4, 2016, registration or registration renewals by mail or fax would no longer be permitted, unless a waiver has been granted for the registrant. Proposed § 1.234 would require updates to be submitted electronically after January 4, 2016, unless a waiver has been granted in § 1.245. Proposed § 1.235 would require cancellations to be submitted electronically after January 4, 2016, unless a waiver has been granted in § 1.245. Proposed § 1.245 also mentions January 4, 2016. Because the final rule is being published after January 4, 2016, we are finalizing §§ 1.231, 1.234, 1.235, and 1.245 without a reference to "January 4, 2016." Furthermore, we note that for reasons stated elsewhere in this **Federal Register** document, we are replacing "January 4, 2016" with "January 4, 2020" in §§ 1.231, 1.234, 1.235, and 1.245 of the final rule.

We are making other changes in §§ 1.231, 1.232, 1.234, and 1.235 of the final rule to improve clarity. The changes are as follows:

- Using "submit" or "submission" instead of "complete" or "completion" in §§ 1.231, 1.234, and 1.235 of the final rule;
- Using "sends" instead of "transmits" in §§ 1.231 and 1.234 of the final rule;
- Adding "you" in §§ 1.231, 1.232, and 1.234 of the final rule to clarify that we are referring to the registrant;
- Deleting language that mentions the registrant not having "reasonable access to the Internet" in §§ 1.231, 1.234, and 1.235 of the final rule;
- Deleting "electronic" and "automatically" in §§ 1.231 and 1.235, respectively, in the final rule.

Furthermore, we stated in proposed §§ 1.231, 1.234, 1.235, and 1.245 that the zip code for our College Park, Maryland address is "20993." In §§ 1.231, 1.234, 1.235, and 1.245 of the final rule, we are correcting the zip code to "20740." In addition, the street has been renamed from "Paint Branch Parkway" to "Campus Drive" and the street number has been changed from "5100" to "5001." Therefore, in the final rule, we are changing the street name and number to "5001 Campus Drive."

B. CD–ROM Submissions

We proposed to delete the option to submit and update multiple registrations by CD–ROM. Specifically, we proposed to remove the option to use CD–ROM for multiple registration submissions in § 1.231(c) as well as the option to use CD–ROM for updates of multiple submissions in § 1.234(e). FDA stated that it proposed to make this change because we tentatively concluded that this method of submitting, updating, and canceling registrations is outdated and obsolete. We did not receive comments on this issue and we are finalizing these changes as proposed.

In addition, in the preamble to the proposed rule, we stated that we were proposing to remove the option to use CD–ROM in § 1.235(e) (*i.e.*, the option for cancellations of multiple registrations). In our proposed regulatory text, however, we inadvertently retained the option to submit multiple cancellations using CD–ROM in § 1.235(e). That was an error, and this final rule removes § 1.235(e) from § 1.235.

XV. Economic Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional costs per entity of this rule are small, the Agency also believes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The final analyses conducted in accordance with these Executive Orders and statutes will be made available in the docket for this rulemaking (Ref. 13).

XVI. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Registration of Food Facilities (OMB Control Number 0910–0502)—Revision.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

Description: In the **Federal Register** of April 9, 2015 (80 FR 19159), we published a notice of proposed rulemaking including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the proposed regulation. In the analysis we invited comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FSMA (Pub. L. 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act to require, among other things, that registrants for food facilities renew registrations biennially (section 415(a)(3) of the FD&C Act). FSMA also amended section 415 of the FD&C Act to require that food facility registrations include the email address for the contact person of a domestic facility and the email address of the United States agent for a foreign facility, as well as an assurance that FDA will be permitted to inspect the facility (section 415(a)(2) of the FD&C Act). These requirements went into effect upon enactment of FSMA. In addition, section 415(a)(2) of the FD&C Act, as amended by FSMA, also provides that, when determined necessary by FDA "through guidance," a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed, or held at such facility, as determined appropriate by FDA, including by guidance. FDA issued a guidance document entitled

"Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" in October 2012.

To comply with the statutory deadline under the provisions of FSMA, FDA initially obtained a 6-month OMB approval of these self-implementing FSMA reporting burdens under the emergency processing provisions of the PRA, and subsequently obtained a 3-year approval of these requirements under the same assigned OMB control number 0910–0502. OMB extended the approval for an additional 3 years in 2013. The current expiration date of the information collection is August 31, 2016.

The final rule will require food facilities to submit certain additional registration information to FDA with initial registrations, updates, and biennial renewals. The final rule will also require mandatory electronic registration submissions beginning in 2020, which we estimate would cause some food facilities to submit a request for a waiver from that requirement. Finally, the final rule will establish certain verification procedures. These requirements are discussed in depth in the preamble to the final rule.

The currently approved reporting burden for food facility registration under OMB control number 0910–0502 is 468,117 hours. The estimated reporting burden for food facility registration under the final rule is 278,382 hours, a decrease of 189,735 hours. This decrease is due in large part to a reduction in the number of registered food facilities, which we believe is reflective of the fact that the 2012 biennial registration renewal cycle appear to have had the effect of removing many out-of-date registrations from the registration system. As discussed in the PRA for the proposed rule, we are making additional changes to the currently approved reporting burden as well. Since obtaining the FSMA-related emergency OMB approval and subsequent 3-year approval, we have refined our estimates for the time required to comply with the self-implementing FSMA provisions. As we explain in detail in the preliminary economic impact analysis, this is in part because we no longer assume that it will take domestic and foreign facilities different amounts of time to comply with the provisions of the proposed rule. It is also in part because the option to submit abbreviated registration renewals did not previously exist and in part because we have revised additional assumptions.

We received many comments regarding requirements of this rule, but none of the comments specifically addressed the four topics about which we invited comments in the PRA analysis that accompanied the proposed rule.

Although FDA is making some generally minor revisions to the proposed rule, we are finalizing most of the key aspects of the proposed rule. The following three changes are substantial enough to require us to revise the estimates in the PRA for the proposed rule: (1) We are clarifying that if a waiver under § 1.245 has been granted from the electronic submission requirement, the facility is not required to submit future waiver requests each time the facility submits a renewal or update; (2) we will continue to allow 60 calendar days to submit updates to registrations in § 1.234, instead of shortening the time period to 30 calendar days as we proposed; and finally (3) we plan to implement a VIS for U.S. agents.

These revisions are necessary to address changes to the proposed regulation included in this final rule, as discussed in the following paragraphs. For more information on our original calculations of the information collection burden associated with this rulemaking, you may refer to the PRA analyses found under Docket No. FDA–2002–N–0323 at *http://www.regulations.gov.*

FDA revises its estimate of the one-time burden of the FSMA-related provisions of this final rule on registered facilities as follows:

TABLE 5—ESTIMATED ONE TIME REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
All facility registrations (1.230–1.233)	172,274	1	172,274	0.18 (11 minutes)	31,009
Waiver requests (1.245)	2,121	1	2,121	0.17 (10 minutes)	361
Total One Time Reporting Burden	....	....	....	....	31,370

[1] There are no operations and maintenance costs associated with one-time recordkeeping burden.

To determine the number of facilities in table 5, we assume that some of the participants in the 2012 biennial registration renewal cycle were new registrants. We do not consider those new registrations in estimating the total burden associated with the FSMA requirements. FDA used the Small Business Administration's (SBA's) estimate that 12 percent of all businesses are new. Although SBA's estimate does not necessarily mean that 12 percent of all food facilities are new, we nevertheless find the SBA's estimate sufficiently relevant to apply to food facilities. We therefore estimate that 12 percent of currently registered food facilities were not registered at the time of the 2012 registration renewal cycle. As such, we estimate that 88 percent of currently registered food facilities, or 172,274 facilities, were already registered in 2012.

Using our updated estimates for the time required to comply with the self-implementing FSMA provisions, we now estimate that the requirement for an email address for a domestic facility's contact person and a foreign facility's U.S. agent will take 1 minute. We also now estimate that the assurance statement required by FSMA will take 5 minutes to provide, and that the post-FSMA changes to food product categories will not result in any additional burden for facilities.

We also estimate the one-time burden from the new data elements in this final rule. We estimate an increase in the average burden per response due to the new data elements required by this final rule. FDA believes that the new information will be readily available to the firms. We estimate that entering the four additional pieces of information that are currently optional will require, on average, an additional minute for each new data element per response. The four additional pieces of information that are currently optional are: (1) Preferred mailing address, (2) email address for the owner operator or agent in charge, (3) type of activity or type of storage conducted at the facility, and (4) email address of the emergency contact of a domestic facility. As explained in the preamble to the final rule, we revised the final rule and no longer require facilities to use D–U–N–S numbers. Instead, the final rule requires the use of a UFI recognized as acceptable by FDA. We are also postponing the requirement to submit a UFI until the registration renewal period beginning October 1, 2020. We estimate that entering a unique facility identifier requires, on average, an additional minute per response. Thus, we estimate that entering these five new data elements will require a total of 5 additional minutes. We estimate that the submission of the FSMA data elements and new data elements will jointly increase the one-time burden from those activities by a total of 11 minutes (0.18 hour). The estimated one-time burden for currently registered facilities is 172,274 facilities × 0.18 hours = 31,009 hours. According to 2014 registration data, 2,121 registrations were from facilities that submitted paper registrations. We believe these same facilities are more likely to request a waiver from the requirement to electronically submit their registration. We estimate that it will take a respondent 10 minutes to prepare the waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the one-time burden of submitting waiver requests is estimated to be 361 hours (2,121 × 0.17 hours), as reported in table 5. The estimated total one-time burden for currently registered facilities is therefore 31,370 hours.

We estimate the annual burden for this information collection as follows:

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
New domestic facility registrations (1.230–1.233)	9,795	1	9,795	2.7	26,447
New foreign facility registrations (1.230–1.233)	13,697	1	13,697	8.7	119,164
Updates (1.234)	53,836	1	53,836	1.2	64,603
Cancellations (1.230(b))	6,390	1	6,390	1	6,390
Biennial renewals (1.235)	97,883	1	97,883	0.38	37,196
Third party registration verification procedure	41,256	1	41,256	0.25	10,314
U.S. Agent verification procedure with VIS	57,070	1	57,070	0.25	14,268
Total Hours	....	....	....	....	278,382

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The currently approved annual reporting burden for food facility registration under OMB control number 0910–0502 is 468,117 hours. The estimated reporting burden for food facility registration under this final rule is 278,382 hours, a decrease of 189,735 hours. This decrease is due to the recently reduced number of active registrations in the food facility registration database.

Our estimates of the number of facilities that will submit new facility registrations are based on estimates by SBA that 12 percent of all businesses each year are new. As such, we estimate that 12 percent of registrations (or 23,500 registrations) are from new facilities entering the market. We are making additional changes to the currently approved reporting burden as well. As discussed previously, FDA obtained a 6-month emergency OMB approval of the self-implementing FSMA reporting burdens, and subsequently obtained a 3-year approval of these requirements. As described in the preliminary economic impact analysis, we estimate that on an annualized basis 97,833 respondents will file biennial renewals, a decrease from the estimated number of 224,930 respondents reported in the 2013 request for extension. These decreases are due to recent reductions in the number of active registrations in the food facility registration database.

Prior to FSMA, FDA estimated that the average burden associated with new domestic and foreign facility registrations was a respective 2.5 and 8.5 hours. (See 75 FR 30033.) We expect that this final rule will add an additional 11 minutes to that burden as a result of the required new data elements. Based on estimates by SBA that 12 percent of all businesses are new, we estimate that all new facilities each year will be equal to 12 percent of the total number of registered facilities. Thus, we estimate that each year there will be 9,795 new domestic and 13,697 new foreign facility registrations, and that the average burden for those new registrations will be of 2.7 hours (2.5 hours plus 11 minutes) for new domestic facility registrations and 8.7 hours (8.5 hours plus 11 minutes) for new foreign facility registrations, as reported in table 6, rows 1 and 2.

This final rule does not shorten the time period for updates from 60 calendar days to 30 calendar days as originally proposed. We are not finalizing our proposal to change the current requirement that updates take places within 30 calendar days; instead, we are continuing to allow 60 calendar days for updates, as provided in current § 1.234. In the PRA analysis for the proposed rule, in which we estimated the burden for the proposed 30-day update requirement, we estimated that 68,518 respondents (70 percent of facilities) would submit updates each year. For a 60-day update requirement, we estimated that the number of respondents was 53,836 per year (55 percent of facilities). The average burden per response for updates remains unchanged as 1.2 hours, as reported in table 6 row 3. In the proposed rule, we also proposed to shorten the time period to submit cancellations from 60 calendar days to 30 calendar days. Although we are not finalizing that proposal, we have not changed our estimate of the average burden per response for cancellations because this final rule does not add new data elements for cancellations.

This final rule also establishes an abbreviated renewal process, which modifies our previous estimate that on average it will take 0.5 hours per renewal. With the option for an abbreviated renewal process, we estimate that half the facilities will take 15 minutes per renewal using the abbreviated renewal process and that half of facilities will take 30 minutes. This alters our previous estimate of 0.5 hours to submit a renewal to an average of 0.38 hours (23 minutes) to submit a renewal, as reported in table 6, row 5. This estimate takes into account that some registered firms will be able to take advantage of the abbreviated renewal process, while other firms will take more time to prepare and submit the renewal, as discussed in the preliminary economic impact analysis.

Furthermore, this final rule also establishes a verification procedure for registrations submitted by individuals other than the owner, operator, or agent in charge (third party registrations), as well as a verification procedure for U.S. agents. In connection with requiring this verification process, this final rule adds email address to the list of required information identifying the individual who authorized submission of registrations submitted by individuals other than the owner, operator, or agent in charge. As described in the preliminary economic impact analysis, we estimate that it takes 15 minutes (0.25 hour) to participate in FDA's verification procedure. We have not changed this estimate. We further estimate that 82,513 registrations will be affected once every other year, or 41,256 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours (41,256 × 0.25 hour = 10,314 hours), as reported in table 6, row 6.

For the U.S. agent verification process, in the PRIA we estimated a resulting burden from the verification procedure to be about 30 minutes (0.5 hours) by 114,139 affected registrations once every 2 years, or 57,070 facility registrations annually. However, this final rule also provides for the creation of a U.S. agent VIS, which we estimate will cut the time for verification procedures for U.S. agents in half (from 30 minutes to 15 minutes). As currently envisioned, the system is designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. Specifically, the system will allow a U.S. agent to directly provide their contact information (that is, the same contact information required for foreign food facility registration) and the name of the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. agent contact information through foreign food facility registrations, many of which are created and updated by the facility, rather than the U.S. agent for the facility. We expect that the system will allow agents to provide their name, full mailing address, phone number, email address, and an emergency contact phone number, as well as the name of the facility or facilities for which the agent agrees to serve. After a U.S. agent provides this information, FDA will provide the agent with an identification number that the agent could provide to foreign facilities it has agreed to represent as a U.S. agent. If a foreign facility uses a U.S. agent identified in the system, the facility will have the option of providing the name and identification number for the U.S. agent in its registration rather than the specific U.S. agent's contact information required for food facility registrations (*e.g.*, address, email address, phone number). After using the identification number, and if the foreign facility name matches a facility name the U.S. agent identified in the system, the U.S. agent contact information in the system will then be linked and automatically populated in the foreign facility registration. When the confirmation copy of a foreign facility registration is sent to the U.S. agent, it will be sent to the contact information provided by the U.S. agent to ensure that the U.S. agent is aware of the connection with each foreign facility registration.

We expect that when a foreign facility uses an identification number for a registered U.S. agent and the name of the facility matches the facility name the agent has identified, that we will consider the use of that identification a verification of U.S. agent information for purposes of the U.S. agent verification step. Thus, we estimate the total annual burden of the foreign facility U.S. agent verifications to be 14,268 hours (57,070 × 0.25 hour = 14,268), as reported in table 6, row 7.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XVII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XVIII. Federalism

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XIX. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, Amendments to Registration of Food Facilities—Preliminary Regulatory Impact Analysis FDA–2002–N–0323, (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM444325.pdf*), April 2015.
2. FDA Memorandum, "FDA Memorandum to Dockets on Records of Outreach," 2013. See Reference 7 to the 2014 supplemental human preventive controls notice.
3. FDA Memorandum, "Memoranda of Outreach," 2015.
4. FDA, "Food CGMP Modernization—A Focus on Food Safety," (*http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm207458.htm*), November 2, 2005. Accessed and printed on March 20, 2015. See Reference 1 to the 2013 proposed human preventive controls rule.
5. FDA, "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm324778.htm*), October 2012. Accessed and printed on April 5, 2016.
6. FDA, "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)," (*http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf*), November 2014. Accessed on May 2, 2016.
7. USDA Agricultural Marketing Service, "Regional Food Hub Resource Guide," (*https://www.ams.usda.gov/sites/default/files/media/Regional%20Food%20Hub%20Resource%20Guide.pdf*), April

2012. Accessed and printed on April 6, 2016.
8. FDA, "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration," Guidance for Industry, (*http://www.fda.gov/downloads/drugs/guidancecompliancere gulatoryinformation/guidances/ucm 421827.pdf*), November 2014. Accessed and printed on April 6, 2016.
9. FDA Memorandum, "D–U–N–S and Registered Facilities," July 9, 2014, from John Gardner, MD, MPH Senior Technical Advisor, Medical Informatics, Office of Informatics and Technology Innovation, Office of Information Management and Technology, Office of Operations.
10. U.S. Government Accountability Office, "Government Is Analyzing Alternatives for Contractor Identification Numbers," (*http://www.gao.gov/assets/600/591551.pdf*), June 2012. Accessed and printed on April 5, 2016.
11. Specially Designated Nationals List (SDN) (*https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx*). Accessed on April 5, 2016.
12. FDA, "FDA's Voluntary Qualified Importer Program," Draft Guidance for Industry, (*http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatory Information/UCM448558.pdf*), June 2015. Accessed and printed on April 6, 2016.
13. FDA, "Amendments to Registration of Food Facilities: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis," 2016.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended to read as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. In § 1.227, revise the definitions for "Retail food establishment" and "U.S. agent" to read as follows:

§ 1.227 What definitions apply to this subpart?

* * * * *

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

* * * * *

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

* * * * *

■ 3. Revise § 1.230 to read as follows:

§ 1.230 When must you register or renew your registration?

(a) *Registration.* You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States. You may authorize an individual to register the facility on your behalf.

(b) *Registration renewal.* You must submit a registration renewal containing the information required under § 1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. You may authorize an individual to renew a facility's registration on your behalf. If the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration renewal, and identifies by name, address, and telephone number, the individual who authorized submission of the registration renewal. In addition, the registration renewal must also identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under § 1.245. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option). Each electronic registration renewal must include the name of the individual submitting the renewal.

(c) *Abbreviated registration renewal process.* If you do not have any changes to the information required under § 1.232 since you submitted the preceding registration, registration renewal, or update for your facility, you may use the abbreviated registration renewal process. If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under § 1.232 since you submitted the preceding registration, registration renewal or update, and you must certify that the information submitted is truthful and accurate. Each abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option). Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under § 1.245. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA.

■ 4. Revise § 1.231 to read as follows:

§ 1.231 How and where do you register or renew your registration?

(a) *Electronic registration and registration renewal.* (1) To register or renew a registration electronically, you must go to *http://www.fda.gov/furls,* which is available for registration 24 hours a day, 7 days a week. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under § 1.245.

(3) After you submit your electronic registration, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's UFI as part of your electronic registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(4) For electronic registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to electronic registration renewals, after completion of the electronic registration renewal, FDA will provide an electronic confirmation of the registration renewal. For electronic registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide an electronic confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(5) For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update information about your U.S. agent as part of your electronic registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) You will be considered registered once FDA electronically sends you your confirmation and registration number.

(b) *Registration or registration renewal by mail or fax.* Beginning January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may register or renew a registration by mail or by fax.

(1) You must register or renew a registration (including abbreviated registration renewals) using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food

Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301–436–2804.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the Agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.

(5) After you submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to registration renewals, after you submit your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration.

(6) For registrations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration by mail or fax, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the submission. With respect to registration renewals, after completion of the registration renewal by mail or fax, FDA will provide a confirmation of the registration renewal. For registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the registration renewal until that individual confirms that he or she authorized the submission.

(7) For a foreign facility, after you submit your registration by mail or fax, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to registration renewals, after you complete your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update information about your U.S. agent as part of your registration renewal, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(8) FDA will mail or fax you a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the Agency (*i.e.*, by mail or fax).

(9) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(10) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Fees.* No registration fee is required.

(d) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

■ 5. Revise § 1.232 to read as follows:

§ 1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

(1) The name, full address, and phone number of the facility;

(2) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;

(3) The preferred mailing address, if different from that of the facility;

(4) The name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(5) All trade names the facility uses;

(6) The name, full address, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under § 1.245;

(7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;

(8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:

(i) Ambient human food storage warehouse/holding facility;

(ii) Refrigerated human food warehouse/holding facility;

(iii) Frozen human food warehouse/holding facility;

(iv) Interstate conveyance caterer/catering point;

(v) Contract sterilizer;

(vi) Labeler/relabeler;

(vii) Manufacturer/processor;

(viii) Acidified food processor;

(ix) Low-acid food processor;

(x) Farm mixed-type facility;

(xi) Packer/repacker;

(xii) Salvage operator (reconditioner);

(xiii) Animal food warehouse/holding facility;

(xiv) Other activity.

(9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act;

(10) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and

telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA has granted a waiver under § 1.245. Each registration must include the name of the individual submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address.

■ 6. Revise § 1.233 to read as follows:

§ 1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit.

■ 7. Revise § 1.234 to read as follows:

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* You must update a facility's registration within 60 calendar days of any change to any of the information previously submitted under § 1.232 (*e.g.,* change of operator, agent in charge, or U.S. agent), except a change of the owner. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under § 1.245.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in § 1.235 within 60 calendar days of the change and the new owner must submit a new registration for the facility as specified in § 1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at *http://www.fda.gov/furls.*

(2) After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the electronic update, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.

(4) Your registration will be considered updated once FDA sends you your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may update your facility's registration by mail or by fax.

(1) You must update your registration using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the Agency (*i.e.,* by mail or fax).

(4) FDA will enter complete and legible updates into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the Agency (*i.e.,* by mail or fax). After you submit your update by mail or fax, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration. FDA will not provide a confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration update by mail or fax, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the registration update until that individual confirms that he or she authorized the update.

(7) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(8) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

■ 8. Revise § 1.235 to read as follows:

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* You must cancel a registration within 60 calendar days of the reason for cancellation (*e.g.,* your facility ceases operations, ceases providing food for consumption in the

United States, or is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and email address (if available) of the individual submitting the cancellation;

(5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under § 1.245; and

(6) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at *http://www.fda.gov/furls.*

(2) Once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation.

(3) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(4) Your registration will be considered cancelled once FDA sends you your cancellation confirmation.

(d) *Cancellation by mail or fax.* Beginning January 4, 2020, you must cancel your registration electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted a waiver under § 1.245, you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the Agency (*i.e.,* by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the Agency (*i.e.,* by mail or fax).

(6) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system. FDA will send you your cancellation confirmation.

■ 9. Revise § 1.241 to read as follows:

§ 1.241 What are the consequences of failing to register, update, renew, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.

(c) FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). If FDA cancels a facility's registration, FDA will send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

(d) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

■ 10. Add § 1.245 to subpart H to read as follows:

§ 1.245 Waiver request.

Under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d), beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement. Under § 1.232(a)(6), you must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement. In addition, under §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS–681), College Park, MD 20740.

Dated: July 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16531 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part VII

Department of Commerce

International Trade Administration

Certain Cold-Rolled Steel Flat Products From Japan and the People's Republic of China: Antidumping Duty Orders and Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Countervailing Duty Order; Notices

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–873, A–570–029]

Certain Cold-Rolled Steel Flat Products From Japan and the People's Republic of China: Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (the Department) and the International Trade Commission (ITC), the Department is issuing antidumping duty orders on certain cold-rolled steel flat products from Japan and the People's Republic of China (PRC).

DATES: *Effective Date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Trisha Tran at (202) 482–4852 (Japan), Scott Hoefke at 202–482–4947 (PRC), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(c), on May 24, 2016, the Department published the final determinations of sales at less than fair value in the antidumping duty investigations of certain cold-rolled steel flat products from Japan and the PRC.[1] On July 7, 2016, the ITC notified the Department of its final determination pursuant to section 735(b)(1)(A)(i) of the Act, that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of imports of certain cold-rolled steel flat products from Japan and the PRC.[2] In addition, the ITC notified the Department of its final determination that critical circumstances do not exist with respect to imports of subject merchandise from Japan and the PRC that are subject to the Department's final affirmative critical circumstances findings.[3]

Scope of the Order: Japan

The products covered by this order are certain cold-rolled (cold-reduced), flat-rolled steel products, whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this order are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free ("IF")) steels, high strength low alloy ("HSLA") steels, motor lamination steels, Advanced High Strength Steels ("AHSS"), and Ultra High Strength Steels ("UHSS"). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. Motor lamination steels contain micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AI–ISS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes cold-rolled steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the order if performed in the country of manufacture of the cold-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this order unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this order:

- Ball bearing steels;[4]

---

[1] *Certain Cold-Rolled Steel Flat Products From Japan: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 81 FR 32721 (May 24, 2016) (*Final Determination*) and accompanying Issues and Decision Memorandum, *see also Certain Cold-Rolled Steel Flat Products from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Affirmative Determination of Critical Circumstances,* 81 FR 32721 (May 24, 2016) (*PRC Final Determination*) 81 FR 32725 (May 24, 2016) and accompanying Issues and Decision Memorandum.

[2] *See* Letter to Christian Marsh, Deputy Assistant Secretary of Commerce for Enforcement and Compliance, from Irving A. Williamson, Chairman of the U.S. International Trade Commission, regarding certain cold-rolled steel flat products from China and Japan (July 7, 2016) (ITC Letter). *See also Cold-Rolled Steel Flat Products from China and Japan (Investigation Nos. 701–TA–541 and 731–TA–1284 and 1286 (Final), USITC Publication 4619, July 2016)* (*Final*).

[3] *Id.*

[4] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not

- Tool steels;[5]
- Silico-manganese steel;[6]
- Grain-oriented electrical steels (“GOES”) as defined in the final determination of the U.S. Department of Commerce in *Grain-Oriented Electrical Steel From Germany, Japan, and Poland*.[7]
- Non-Oriented Electrical Steels (“NOES”), as defined in the antidumping orders issued by the U.S. Department of Commerce in *Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan*.[8]

Also excluded from the scope of this order is ultra-tempered automotive steel, which is hardened, tempered, surface polished, and meets the following specifications:

- Thickness: less than or equal to 1.0 mm;
- Width: less than or equal to 330 mm;
- Chemical composition:

Element	C	Si	Mn	P	S
Weight %	0.90–1.05	0.15–0.35	0.30–0.50	Less than or equal to 0.03	Less than or equal to 0.006.

- Physical properties:

Width less than or equal to 150mm.	Flatness of less than 0.2% of nominal strip width.
Width of 150 to 330mm.	Flatness of less than 5 mm of nominal strip width.

- Microstructure: Completely free from decarburization. Carbides are spheroidal and fine within 1% to 4% (area percentage) and are undissolved in the uniform tempered martensite;
- Surface roughness: Less than or equal to 0.80 μm Rz;
- Non-metallic inclusion:
  - Sulfide inclusion less than or equal to 0.04% (area percentage)
  - Oxide inclusion less than or equal to 0.05% (area percentage); and
- The mill test certificate must demonstrate that the steel is proprietary grade “PK” and specify the following:
  - The exact tensile strength, which must be greater than or equal to 1600 N/mm^2;
  - The exact hardness, which must be greater than or equal to 465 Vickers hardness number;
  - The exact elongation, which must be between 2.5% and 9.5%; and
  - Certified as having residual compressive stress within a range of 100 to 400 N/mm^2.

The products subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (“HTSUS”) under item numbers: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050. The products subject to the order may also enter under the following HTSUS numbers: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and CBP purposes only. The written description of the scope of the order is dispositive.

Scope of the Order: PRC

The products covered by this order are certain cold-rolled (cold-reduced), flat-rolled steel products, whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (“width”) of 12.7 mm or greater, regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*,

---

less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[5] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[6] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

[7] *See Grain-Oriented Electrical Steel From Germany, Japan, and Poland: Final Determinations of Sales at Less Than Fair Value and Certain Final Affirmative Determination of Critical Circumstances*, 79 FR 42,501, 42,503 (July 22, 2014) (“*Grain-Oriented Electrical Steel From Germany, Japan, and Poland*”). This determination defines grain-oriented electrical steel as “a flat-rolled alloy steel product containing by weight at least 0.6 percent but not more than 6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, in coils or in straight lengths.”

[8] *See Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan: Antidumping Duty Orders*, 79 FR 71,741, 71,741–42 (December 3, 2014) (“*Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan*”). The orders define NOES as “cold-rolled, flat-rolled, alloy steel products, whether or not in coils, regardless of width, having an actual thickness of 0.20 mm or more, in which the core loss is substantially equal in any direction of magnetization in the plane of the material. The term ‘substantially equal’ means that the cross grain direction of core loss is no more than 1.5 times the straight grain direction (*i.e.*, the rolling direction) of core loss. NOES has a magnetic permeability that does not exceed 1.65 Tesla when tested at a field of 800 A/m (equivalent to 10 Oersteds) along (*i.e.*, parallel to) the rolling direction of the sheet (*i.e.*, B800 value). NOES contains by weight more than 1.00 percent of silicon but less than 3.5 percent of silicon, not more than 0.08 percent of carbon, and not more than 1.5 percent of aluminum. NOES has a surface oxide coating, to which an insulation coating may be applied.”

in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been "worked after rolling" (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this order are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. Motor lamination steels contain micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes cold-rolled steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the order if performed in the country of manufacture of the cold-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this order unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this order:

- Ball bearing steels;[9]
- Tool steels;[10]
- Silico-manganese steel;[11]
- Grain-oriented electrical steels (GOES) as defined in the final determination of the U.S. Department of Commerce in Grain-Oriented Electrical Steel From Germany, Japan, and Poland.[12]
- Non-Oriented Electrical Steels (NOES), as defined in the antidumping orders issued by the U.S. Department of Commerce in Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan.[13]

The products subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050. The products subject to the order may also enter under the following HTSUS numbers: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000.

---

[9] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[10] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[11] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

[12] *See* Grain-Oriented Electrical Steel From Germany, Japan, and Poland: Final Determinations of Sales at Less Than Fair Value and Certain Final Affirmative Determination of Critical Circumstances, 79 FR 42501, 42503 (Dep't of Commerce, July 22, 2014). This determination defines grain-oriented electrical steel as "a flat-rolled alloy steel product containing by weight at least 0.6 percent but not more than 6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, in coils or in straight lengths."

[13] *See* Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan: Antidumping Duty Orders, 79 FR 71741, 71741–42 (Dep't of Commerce, December 3, 2014). The orders define NOES as "cold-rolled, flat-rolled, alloy steel products, whether or not in coils, regardless of width, having an actual thickness of 0.20 mm or more, in which the core loss is substantially equal in any direction of magnetization in the plane of the material. The term 'substantially equal' means that the cross grain direction of core loss is no more than 1.5 times the straight grain direction (*i.e.,* the rolling direction) of core loss. NOES has a magnetic permeability that does not exceed 1.65 Tesla when tested at a field of 800 A/m (equivalent to 10 Oersteds) along (*i.e.,* parallel to) the rolling direction of the sheet (*i.e.,* B800 value). NOES contains by weight more than 1.00 percent of silicon but less than 3.5 percent of silicon, not more than 0.08 percent of carbon, and not more than 1.5 percent of aluminum. NOES has a surface oxide coating, to which an insulation coating may be applied."

The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the order is dispositive.

Antidumping Duty Order

In accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC has notified the Department of its final determination in this investigation, in which it found that imports of certain cold-rolled steel flat products from Japan and the PRC are materially injuring a U.S. industry.[14] Therefore, in accordance with section 735(c)(2) of the Act, we are publishing these antidumping duty orders. Because the ITC determined that imports of certain cold-rolled steel flat products from Japan and the PRC are materially injuring a U.S. industry, unliquidated entries of such merchandise from Japan and the PRC, entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties.

As a result of the ITC's final determination, in accordance with section 736(a)(1) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by the Department, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of certain cold-rolled steel flat products from Japan and the PRC. These antidumping duties will be assessed on unliquidated entries from Japan and the PRC entered, or withdrawn from warehouse, for consumption on or after March 7, 2016, the date on which the Department published the *Preliminary Determinations*,[15] but will not include entries occurring after the expiration of the provisional measures period and before publication of the ITC's final injury determination, as further described below.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we will instruct CBP to continue to suspend liquidation on entries of subject merchandise from Japan and the PRC. We will also instruct CBP to require cash deposits equal to the estimated amount by which the normal value exceeds the U.S. price as indicated in the chart below, adjusted where appropriate for export subsidies and estimated domestic subsidy pass-through.[16] These instructions suspending liquidation will remain in effect until further notice.

We will also instruct CBP to require cash deposits at rates equal to the estimated weighted-average dumping margins indicated below. Accordingly, effective on the date of publication of the ITC's final affirmative injury determinations, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit at rates equal to the estimated weighted-average dumping margins listed below.[17] The relevant all-others rate (for Japan) or the rate for the PRC-wide entity (for the PRC), as applicable, apply to all producers or exporters not specifically listed. For the purpose of determining cash deposit rates, the estimated weighted-average dumping margins for imports of subject merchandise from the PRC will be adjusted, as appropriate, for export subsidies found in the final determination of the companion countervailing duty investigation of this merchandise imported from the PRC.[18]

Provisional Measures

Section 733(d) of the Act states that instructions issued pursuant to an affirmative preliminary determination may not remain in effect for more than four months except where exporters representing a significant proportion of exports of the subject merchandise request the Department to extend that four-month period to no more than six months. In the underlying investigation, the Department published the *Preliminary Determinations* on March 7, 2016.[19] Therefore, the four-month period beginning on the date of the publication of the *Preliminary Determinations* ended on July 4, 2016. Furthermore, section 737(b) of the Act states that definitive duties are to begin on the date of publication of the ITC's final injury determination. Therefore, in accordance with section 733(d) of the Act and our practice, we will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of certain cold-rolled steel flat products from Japan and the PRC entered, or withdrawn from warehouse, for consumption after July 4, 2016, the date the provisional measures expired, and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**.

Estimated Weighted-Average Dumping Margin

The weighted-average antidumping duty margin percentages are as follows:

Exporter/producer	Weighted-average margin (percent)
Japan:	
JFE Steel Corporation	71.35
Nippon Steel & Sumitomo Metal Corporation	71.35
All-Others	71.35
PRC:	
PRC-Wide Entity	265.79

Critical Circumstances

With regard to the ITC's negative critical circumstances determination on imports of certain cold-rolled steel from Japan and the PRC, we will instruct CBP to lift suspension and to refund any cash deposit made to secure the payment of estimated antidumping duties with respect to entries of the merchandise entered, or withdrawn from warehouse, for consumption on or after December 8, 2015 (*i.e.*, 90 days prior to the date of publication of the preliminary determinations), but before March 7, 2016, the publication date of the preliminary determinations.

---

[14] *See* ITC Letter.

[15] *See Certain Cold-Rolled Steel Flat Products From Japan: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Preliminary Affirmative Determination of Critical Circumstances*, 81 FR 11747 (March 7, 2016); *Antidumping Duty Investigation of Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Affirmative Preliminary Determination of Sales at Less Than Fair Value, and Preliminary Affirmative Determination of Critical Circumstances*, 71 FR 11751 (March 7, 2016) (collectively, *Preliminary Determinations*).

[16] *See PRC Final Determination*, 81 FR at 32726 (describing the adjustments to the antidumping duty margins in more detail); *see also* sections 772(c)(1)(C) and 777A(f) of the Act, respectively. Unlike in administrative reviews, the Department calculates the adjustment for export subsidies in investigations not in the margin calculation program, but in the cash deposit instructions issued to CBP. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value, and Negative Determination of Critical Circumstances: Certain Lined Paper Products from India*, 71 FR 45012 (August 8, 2006), and accompanying Issues and Decision Memorandum at Comment 1.

[17] *See* section 736(a)(3) of the Act.

[18] *See Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Partial Affirmative Critical Circumstances Determination*, 81 FR 32729 (May 24, 2016).

[19] *See Preliminary Determinations*.

Notification to Interested Parties

This notice constitutes the antidumping duty orders with respect to certain cold-rolled steel flat products from Japan and the PRC pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at *http://www.trade.gov/enforcement/*.

These orders are published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: July 11, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–16798 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–030]

Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (the Department) and the International Trade Commission (ITC), the Department is issuing a countervailing duty order on certain cold-rolled steel flat products (cold-rolled steel) from the People's Republic of China (PRC).

DATES: *Effective Date:* July 14, 2016.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas at (202) 482–3813 or John Corrigan at (202) 482–7438, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 24, 2016, the Department published its final determination in the countervailing duty investigation of cold-rolled steel from the PRC.[1] On July 7, 2016, the ITC notified the Department of its final determination pursuant to section 705(b)(1)(A)(i) and section 705(d) of the Tariff Act of 1930, as amended (Act), that an industry in the United States is materially injured by reason of subsidized imports of cold-rolled steel from the PRC, and its determination pursuant to section 705(b)(4)(A) of the Act that critical circumstances do not exist with respect to imports of subject merchandise from the PRC that are subject to the Department's affirmative critical circumstances finding, in part.[2]

Scope of the Order

The products covered by this order are certain cold-rolled (cold-reduced), flat-rolled steel products, whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement ("width") of 12.7 mm or greater, regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, *etc.*). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.*, products which have been "worked after rolling" (*e.g.*, products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, *etc.*), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this order are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. Motor lamination steels contain micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes cold-rolled steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the cold-rolled steel.

---

[1] *See Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Partial Affirmative Critical Circumstances Determination*, 81 FR 32729 (May 26, 2016) (*Final Determination*).

[2] *See* Letter to Christian Marsh, Deputy Assistant Secretary of Commerce for Enforcement and Compliance, from Irving A Williamson, Chairman of the U.S. International Trade Commission, regarding certain cold-rolled steel flat products from China and Japan (July 7, 2016) (ITC Letter). *See also Cold-Rolled Steel Flat Products from China and Japan (Investigation Nos. 701–TA–541 and 731–TA–1284 and 1286 (Final), USITC Publication 4619, July 2016)* (*Final*).

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this order:

- Ball bearing steels;[3]
- Tool steels;[4]
- Silico-manganese steel;[5]
- Grain-oriented electrical steels (GOES) as defined in the final determination of the U.S. Department of Commerce in *Grain-Oriented Electrical Steel From Germany, Japan, and Poland*.[6]
- Non-Oriented Electrical Steels (NOES), as defined in the antidumping orders issued by the U.S. Department of Commerce in *Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan*.[7]

The products subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050.

The products subject to this order may also enter under the following HTSUS numbers: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the order is dispositive.

Countervailing Duty Order

In accordance with sections 705(b)(1)(A)(i) and 705(d) of the Act, the ITC has notified the Department of its final determination in this investigation, in which it found that imports of certain cold-rolled steel flat products from the PRC are materially injuring a U.S. industry.[8] Therefore, in accordance with section 705(c)(2) of the Act, we are publishing this countervailing duty order.

In accordance with section 706(a) of the Act, the Department will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by the Department, countervailing duties on unliquidated entries of cold-rolled steel from the PRC entered, or withdrawn from warehouse, for consumption on or after December 22, 2015, the date on which the Department published its preliminary countervailing duty determinations in the **Federal Register**,[9] and before April 20, 2016, the date on which the Department instructed CBP to discontinue the suspension of liquidation in accordance with section 703(d) of the Act. Section 703(d) of the Act states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than four months. Therefore, entries of cold-rolled steel made on or after April 20, 2016, and prior to the date of publication of the ITC's final determination in the **Federal Register** are not liable for the assessment of countervailing duties due to the Department's discontinuation, effective April 20, 2016, of the suspension of liquidation.

Suspension of Liquidation

In accordance with section 706 of the Act, the Department will direct CBP to reinstitute the suspension of liquidation of cold-rolled steel from the PRC, effective on the date of publication of the ITC's notice of final determination in the **Federal Register**, and to assess, upon further instruction by the Department pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates for the subject merchandise. On or after the date of publication of the ITC's final injury determinations in the **Federal Register**, CBP must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the rates noted below:

---

[3] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[4] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[5] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

[6] *Grain-Oriented Electrical Steel From Germany, Japan, and Poland: Final Determinations of Sales at Less Than Fair Value and Certain Final Affirmative Determination of Critical Circumstances*, 79 FR 42501, 42503 (Dep't of Commerce, July 22, 2014). This determination defines grain-oriented electrical steel as "a flat-rolled alloy steel product containing by weight at least 0.6 percent but not more than 6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, in coils or in straight lengths."

[7] *Non-Oriented Electrical Steel From the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan: Antidumping Duty Orders*, 79 FR 71741, 71741–42 (Dep't of Commerce, Dec. 3, 2014). The orders define NOES as "cold-rolled, flat-rolled, alloy steel products, whether or not in coils, regardless of width, having an actual thickness of 0.20 mm or more, in which the core loss is substantially equal in any direction of magnetization in the plane of the material. The term 'substantially equal' means that the cross grain direction of core loss is no more than 1.5 times the straight grain direction (*i.e.*, the rolling direction) of core loss. NOES has a magnetic permeability that does not exceed 1.65 Tesla when tested at a field of 800 A/m (equivalent to 10 Oersteds) along (*i.e.*, parallel to) the rolling direction of the sheet (*i.e.*, B800 value). NOES contains by weight more than 1.00 percent of silicon but less than 3.5 percent of silicon, not more than 0.08 percent of carbon, and not more than 1.5 percent of aluminum. NOES has a surface oxide coating, to which an insulation coating may be applied."

[8] *See* ITC Letter.

[9] *See Countervailing Duty Investigation of Certain Cold-Rolled Steel Flat Products From the People's Republic of China: Preliminary Affirmative Determination, Preliminary Partial Affirmative Critical Circumstances Determination, and Alignment of Final Determination With Final Antidumping Duty Determination*, 80 FR 79558 (December 22, 2015) (*Preliminary Determination*).

Exporter/producer	Subsidy rate (percent)
Angang Group Hong Kong Co., Ltd	256.44
Benxi Iron and Steel (Group) Special Steel Co., Ltd	256.44
Qian'an Golden Point Trading Co., Ltd	256.44
All-Others	256.44

Critical Circumstances

With regard to the ITC's negative critical circumstances determination on imports of cold-rolled steel from the PRC, we will instruct CBP to lift suspension and to refund any cash deposits made to secure the payment of estimated countervailing duties with respect to entries of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after September 23, 2015 (*i.e.,* 90 days prior to the date of the publication of the CVD *Preliminary Determination*), but before December 22, 2015 (*i.e.,* the date of publication of the CVD *Preliminary Determination*).

Notifications to Interested Parties

This notice constitutes the countervailing duty order with respect to cold-rolled steel from the PRC pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room B8024 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: July 11, 2016.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–16794 Filed 7–13–16; 8:45 am]

BILLING CODE 3510–DS–P

Reader Aids

Federal Register

Vol. 81, No. 135

Thursday, July 14, 2016

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, JULY

42983–43462	1
43463–43926	5
43927–44206	6
44207–44488	7
44489–44758	8
44759–44980	11
44981–45224	12
45225–45386	13
45387–45962	14

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:	
9466	44127
9467	45385
Executive Orders:	
13732	44485

6 CFR

27	42987

7 CFR

319	45387
925	44759
989	44761
1590	43006
1942	43927
Proposed Rules:	
319	44801

8 CFR

270	42987
274a	42987
280	42987

9 CFR

327	45225
Proposed Rules:	
94	43115

10 CFR

2	43019
13	43019
429	43404, 45387
430	43404, 45387
Proposed Rules:	
20	43959

12 CFR

19	43021
109	43021
1002	44764
1209	43028
1217	43031
1250	43028
Proposed Rules:	
1016	44801
1232	43530

14 CFR

1	43463
11	43463
13	43463
23	43469
25	43471, 45405
39	43037, 43472, 43475, 43479, 43481, 43483, 44207, 44489, 44492, 44494, 44496, 44499, 44503, 44981, 44983, 44987, 44990, 44994, 44996
71	43038, 45407
97	44765, 44767
121	43463
125	43463
135	43463
382	43463
406	43463
1214	43040
Proposed Rules:	
39	43120, 43122, 44232, 44235, 44238, 44241, 44244, 44246, 44812, 45070, 45072, 45075
71	43124
139	45872

15 CFR

730	44770
736	44770
738	44770
746	44770
Proposed Rules:	
801	43126

17 CFR

201	43042
232	43047
Proposed Rules:	
229	43130
230	43130
240	43130
275	43530

18 CFR

39	44998
250	43937
385	43937
Proposed Rules:	
375	43557
388	43557

19 CFR

Proposed Rules:	
102	44555
149	43961

20 CFR

404	43048
655	43430
702	43430
725	43430
726	43430
Proposed Rules:	
404	45079
405	45079
416	45079

21 CFR

1	45912
14	45409
20	45409
101	43061
876	45229
882	44771

Proposed Rules:
1.....43155
1005.....43155
1271.....43155

24 CFR

Proposed Rules:
982.....44100

25 CFR

575.....43941

26 CFR

1.....44508, 45008
301.....43488, 45012, 45409
602.....45008, 45012

Proposed Rules:
1.....43567, 44557, 45088
301.....44557

27 CFR

16.....43062

28 CFR

0.....43065
11.....43942
94.....44515

29 CFR

5.....43430
500.....43430
501.....43430
503.....42983
530.....43430
570.....43430
578.....43430
579.....43430
801.....43430
825.....43430
1902.....43430
1903.....43430
2550.....44773, 44784
2560.....43430
2575.....43430
2590.....43430

30 CFR

100.....43430
550.....43066
553.....43066
723.....44535
724.....44535
845.....44535
846.....44535
1202.....43338
1206.....43338

Proposed Rules:
914.....45425
916.....45426

31 CFR

356.....43069
501.....43071
535.....43071
536.....43071
537.....43071
538.....43071
539.....43071
541.....43071
542.....43071
543.....43071
544.....43071
546.....43071
547.....43071
548.....43071
549.....43071
560.....43071
561.....43071
566.....43071
576.....43071
588.....43071
592.....43071
593.....43071
594.....43071
595.....43071
597.....43071
598.....43071

32 CFR

706.....43077

33 CFR

27.....42987
97.....45012
100.....43079, 43488, 43947, 45013, 45015, 45018
117.....43947, 44541, 45018, 45020, 45232
147.....43947, 45018
160.....45012
165.....43079, 43085, 43087, 43089, 43947, 44209, 45018, 45022, 45414

Proposed Rules:
100.....44815
110.....45428
164.....44817
165.....43178, 44825

34 CFR

Proposed Rules:
200.....44928, 44958

36 CFR

2.....45024
1235.....45249
1236.....45249
1237.....45249

38 CFR

38.....44792

Proposed Rules:
38.....44827

39 CFR

Proposed Rules:
111.....43965

40 CFR

Ch. I.....43492
9.....45416
19.....43091
52.....43096, 43490, 43894, 44210, 44542, 44795, 45417, 45419, 45421
60.....43950, 44212, 45232
63.....45232
81.....44210, 45039
180.....43097
228.....44220
721.....44797, 45416
1065.....43101

Proposed Rules:
51.....43180
52.....43180, 43568, 44830, 44831, 45428, 45438, 45447
63.....45089
228.....45262

41 CFR

50–201.....43430

42 CFR

8.....44712
88.....43510
401.....44456

Proposed Rules:
8.....44576
401.....43790
405.....43790
409.....43714
416.....45604
419.....45604
422.....43790
423.....43790
478.....43790
482.....45604
484.....43714
486.....45604
488.....45604
495.....45604

44 CFR

Proposed Rules:
67.....43568

45 CFR

Proposed Rules:
75.....45270

46 CFR

1.....43950, 44230
10.....43950, 44230
11.....43950, 44230
12.....43950, 44230
13.....43950, 44230
14.....44230
15.....43950, 44230
97.....45012

47 CFR

Ch. I.....43956
1.....43523, 44414
4.....45055
54.....44414
73.....43101, 43955, 44231

Proposed Rules:
4.....45095
54.....45447

48 CFR

Ch. 1.....45832, 45868
1.....45833
2.....45833, 45852
4.....45866
8.....45854
15.....45833, 45852
16.....45852
19.....45833
31.....45852
42.....45852
52.....45833, 45852, 45856
53.....45855
538.....43956
552.....43956

Proposed Rules:
915.....43971
934.....43971
942.....43971
944.....43971
945.....43971
952.....43971
1032.....45118
1052.....45118

49 CFR

209.....43101, 43105
213.....43105
214.....43105
215.....43105
216.....43105
217.....43105
218.....43105
219.....43105
220.....43105
221.....43105
222.....43105
223.....43105
224.....43105
225.....43105
227.....43105
228.....43105
229.....43105
230.....43105
231.....43105
232.....43105
233.....43105
234.....43105
235.....43105
236.....43105
237.....43105
238.....43105
239.....43105
240.....43105
241.....43105
242.....43105
243.....43105
244.....43105
272.....43105
392.....43957
578.....43524
1503.....42987

50 CFR

622.....45068, 45245
635.....44798
648.....43957
679.....45423

Proposed Rules:
17.....43972
32.....45790
223.....43979
224.....43979
665.....44249
679.....44251

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List July 8, 2016

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.